MicroPace

Micropace ORLab™

EP Cardiac Stimulator/ Recorder System

USER INSTRUCTION MANUAL

CE
0120

Distributed by:

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CAUTION

US Federal Law restricts this device to sale by or on the order of a physician.

ORLab™ EP Cardiac Stimulator

User Instruction Manual

Micropace Model: EPS320-ORLab1

Micropace Order No.: MP3309

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Table of Contents

1. INTRODUCTION & ESSENTIAL PRESCRIBING INFORMATION 1
1.1 DEVICE DESCRIPTION 1
1.1.1 Description of system 1
1.1.2 Intended Use 1
1.1.3 Indications for Use 1
1.1.4 Contraindications 1
1.1.5 Compatible Equipment 2
1.2 IMPORTANT PATIENT SAFETY WARNINGS 3
1.2.1 General Warning 3
1.2.2 Warnings Specific to the ORLab™ Cardiac Stimulator 4
1.2.3 Warnings Related to the use of ORLab™ Stimulator with RF Ablation Equipment 5
1.3 GENERAL PRECAUTIONS IN HANDLING STIMULATOR 5
1.4 ADVERSE EVENTS 7
1.4.1 Observed Adverse Events 7
1.5 POTENTIAL ADVERSE EVENTS 8
1.6 SUMMARY OF ORLAB'S EPS320 STIMULUS GENERATOR UNIT FIELD TRIAL 10
1.7 INDIVIDUALIZATION OF TREATMENT & PATIENT COUNSELING INFORMATION 11
1.8 REFERENCES 12

2. DEVICE RATINGS, CLASSIFICATION AND CERTIFICATION 13

3. COPYRIGHT, WARRANTY AND DISCLAIMER NOTICE 14

4. EXPLANATION OF SYMBOLS 15

5. INSTALLATION INSTRUCTIONS 21
5.1 TECHNICAL DESCRIPTION 21
5.2 WHO MAY INSTALL THE ORLAB™ 22
5.3 HOW ORLAB™ SUPPLIED 22
5.4 STIMULATOR OPTIONS 23
5.5 CONNECT SYSTEM COMPONENTS 24

6. VERIFYING THE SYSTEM 27
6.1 TRAIN CUSTOMER 28
6.2 MICROPACE ORLAB™ INSTALLATION CHECKSHEET 29

7. USING THE ORLAB™ CARDIAC STIMULATOR 31
7.1 SWITCHING ON AND OFF THE SYSTEM 31
7.2 USING THE COMPUTER 31
7.3 USING THE TOUCH DISPLAY 32

8. USING THE ORLAB™ SOFTWARE 34
8.1 SCREEN PAGE LAYOUT 34
8.2 STARTING A NEW STUDY 34
8.3 ORLAB™ HELP FACILITY 35
8.4 MAIN STUDY PAGE - SENSE PACE PROTOCOL 36
8.4.1 Controls include: 36
8.4.2 Conduction Block Determination 37
8.4.3 Pacing threshold measurement 38
8.4.4 Synchronizing start of pacing to PQRS 38
8.4.5 Contact Test 38
8.4.6 Peak Detection / QRS detection 39
8.4.7 Peak to peak interval / RR Display 39
8.4.8 Amplitude Measurement & Display 39
8.4.9 Ablation State labels: "Pre" and "Post" 40
8.5 BURST STIMULATION PROTOCOL 41
8.5.1 Controls include: 41
8.5.2 Burst Stim Button Safety Delay Tone 42
8.6 EMERGENCY PACE 43
8.7 REVIEWING ECG'S 44
8.7.1 Calipers 45

8.7.2 Saving ECG Data *45*
8.7.3 Loading Stored ECG Data *45*
8.8 PRINTING ECG'S 46
8.9 CONFIGURING ORLAB™ PROTOCOLS 48
8.9.1 Setup available for Sense Pace Protocol *48*
8.9.2 Setup Page for Burst Stim Protocol *52*
8.10 SERVICE SET UP ON ENTRY SCREEN – ADMINISTRATION PAGE 53
8.11 KEYBOARD AND NUMERIC KEYPAD 55

9. THE EPS320 STIMULUS GENERATOR UNIT 56
9.1 STIMULUS GENERATOR UNIT LAYOUT 56
9.2 STIMULATOR CONNECTIONS 58
9.3 HARDWARE ERROR MESSAGES ON THE STIMULUS GENERATOR UNIT 60

10. TROUBLESHOOTING 62

11. MAINTENANCE 64
11.1 BATTERIES 64
11.2 MAINTENANCE AND CALIBRATION 64
11.3 CLEANING INSTRUCTIONS 65
11.4 SERVICEABLE LIFE AND DISPOSAL 66

12. ORLAB™ SPECIFICATIONS 67

13. MANUFACTURER'S GUIDANCE AND DECLARATION–ELECTROMAGNETIC EMISSIONS 68
13.1 CABLE LENGTHS 68
13.2 EMI / EMC SPECIFICATIONS 69

Tables

TABLE 1 RESULTS FOR INDIVIDUAL MEASURED PARAMETERS 11
TABLE 2 EXPLANATION OF SYMBOLS 16
TABLE 3 EXPLANATION OF SYMBOLS – SPECIFIC TO THE ORLAB™ SGU 18
TABLE 4 EXPLANATION OF SYMBOLS IN ORLAB™ SOFTWARE 20
TABLE 5 MICROPACE INSTALLATION CHECKSHEET 30
TABLE 6 COMPUTER FRONT PANEL EXPLANATIONS 31
TABLE 7 SUMMARY OF MAIN TOUCH BUTTONS AND THEIR FUNCTIONS 33
TABLE 8 TABULATED ERROR MESSAGES 61

Figures

FIGURE 1 ORLAB™ EP STIMULATOR / RECORDER SYSTEM (NB: PICTURED WITH WHEELED CART AND ABLATION EQUIPMENT SUPPLIED SEPARATELY FROM ATRICURE INC.) 21
FIGURE 2 ORLAB™ COMPONENTS AND SCHEMATIC 22
FIGURE 3 ORLAB™ QUICK INSTALLATION GUIDE – FRONT AND BACK PAGES. 25
FIGURE 4 ORLAB™ QUICK INSTALLATION GUIDE – INSIDE DOUBLE PAGE SHOWING CONNECTIONS. 26
FIGURE 5 ORLAB™ THREE SYSTEMS FOR BACKUP PACING 28
FIGURE 6 COMPUTER FRONT PANEL 31
FIGURE 7 STIMULUS PARAMETER ADJUSTMENT 32
FIGURE 8 EMERGENCY PACE 32
FIGURE 9 ON-SCREEN NUMERIC KEYPAD AND KEYBOARD FOR DATA ENTRY 32
FIGURE 10 CURRENT STUDY ENTRY PAGE 34
FIGURE 11 EXAMPLE OF AN ORLAB HELP PAGE. 35
FIGURE 12 SENSE-PAGE PROTOCOL EXPLAINED 37
FIGURE 13 BURST STIM PROTOCOL WITH STIM DURATION AND SPECIFIC ABLATION LABELS 42
FIGURE 14 BURST PACE SAFETY DELAY 42
FIGURE 15 EMERGENCY PACE PROTOCOL 43
FIGURE 16 REVIEW SCREEN WITH EXPLANATIONS 44
FIGURE 17 EXAMPLE OF A PRINTOUT 47
FIGURE 18 SENSE PACE PROTOCOL SETUP SCREEN 48
FIGURE 19 ECG PEAK DETECTION PARAMETERS 50
FIGURE 20 BURST STIM SETUP PAGE 52
FIGURE 21 ADMINISTRATION PAGE 54
FIGURE 22 THE EPS320 STIMULUS GENERATOR UNIT FRONT PANEL 56
FIGURE 23 STIMULATOR OUTPUT CHARACTERISTICS 57
FIGURE 24 CONNECTORS ON REAR PANEL OF STIMULUS GENERATOR UNIT 58

Glossary and Terms

Term	Explanation
Drive Train	Also called S1; the 6-8 regular pacing stimuli before any extra-stimuli is applied.
ECG	Electrocardiogram
EP	Electrophysiology
IECG	Intra-cardiac Electrocardiogram
LCD	Liquid Crystal Display
LED	Light Emitting Diode
P/QRS	P wave or QRS; also signifies any IECG waveform.
PC	Personal Computer
RA	Right Atrium
RV	Right Ventricle
RF	Radiofrequency, e.g. RF Ablation
RR	R-R interval on ECG or peak-to-peak interval on IECG.
S1	Basic stimulation interval.
SGU	Micropace Stimulus Generator Unit
SNRT	Sinus Node Recovery Times
StimLink™	Communication cable for connection to EP Recording Equipment
Sx	The name for and the coupling interval of one or more extra-stimuli added after Drive Train called S2, S3…S7.
ppm	Pulses per minute
bpm	Beats per minute
GUI	Graphical User Interface
/min	Events per minute

1. INTRODUCTION & ESSENTIAL PRESCRIBING INFORMATION

1.1 Device Description

1.1.1 Description of system

The ORLab™ is a programmable diagnostic cardiac stimulator with electrocardiogram display tailored for use as a diagnostic tool during surgical and RF ablation procedures for the treatment of arrhythmias in cardiothoracic theaters and hospital electrophysiological laboratories.

No part of the ORLab or its accessories is intended to contact the patient, instead, pacing stimuli are delivered, and ECG signal recorded, via third party products, which may include transvenous endocardial electrode catheters or epicardial mapping and ablation wands.

The ORLab™ device belongs to the Micropace EPS320 product family (Models EPS320B, StimLab™ and ORLab™), which are all based on the EPS320 stimulus generator unit (SGU). The EPS320 SGU is a two channel, mains and battery powered microprocessor-based cardiac stimulator, manually controllable from its front panel. In normal use, however, it is controlled by a separate computer using a variety of user interfaces and computer accessories according to the product model. The ORLab™ model uses a single touch-activated graphical user interface (GUI) to control, display and record results of diagnostic stimulation with the option of printing of selected ECG signals to a laser printer.

The ORLab™ computer interface is optimized for the subset of electrophysiological procedures performed in cardiothoracic operating rooms, which require greater ECG display functionality but simpler stimulation protocols than do the procedures typically performed in the EP laboratory. Three ECG channels are displayed, one surface ECG channel derived from a third party ECG monitor and two intra-cardiac channels from the two pacing channels of the ORLab's EPS320 SGU. ECG data is continuously recorded in a circular 80s buffer and may be captured for review, measured and printed to an external laser printer along with user text comments.

ORLab's two main stimulation protocols include Pace-Sense protocol, suitable for physiological pacing within the range of 30 to 350 ppm, as well as determination of pacing threshold. The second protocol, Burst Stim allows burst overdrive stimulation of arrhythmias and induction of fibrillation with pacing rates from 100 to 1800 ppm. Stimulation protocols with extra-stimuli, incremental or decremental pacing and repetitive stimulation are also available from a background menu.

1.1.2 Intended Use

The EP320 stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

1.1.3 Indications for Use

The ORLab™ Stimulator System is an electrical stimulus generator for diagnostic cardiac stimulation during electrophysiological testing of the human heart.

1.1.4 Contraindications

Do not use the ORLab™ system for life support in patients with life-threatening bradycardia; use instead temporary external pacemaker.

1.1.5 Compatible Equipment

The primary function of the ORLab™ Cardiac Stimulator is the generation of constant current predominantly rectangular stimulation pulses with amplitudes of 0.1 to 25mA, duration of 0.5 to 10ms and with a maximum voltage of +/- 27V. Third party switching equipment with the following special characteristics must be used to carry the stimulus pulses to the intracardiac electrodes without significant distortion:

- Series resistance: < 100 Ohms at up to +/- 25mA
- Shunt resistance: > 100,000 Ohms at up to +/- 27V
- Frequency bandwidth: DC to 300 Hz
- Interference RF energy sources: < 350Vpp at 400 kHz to 600 kHz, or 150W into a 300 Ohm load

Higher series resistance reduces maximum attainable pulse current amplitude; lower shunt resistance reduces delivery of current in all ranges; reduced frequency bandwidth may alter efficacy of stimulation at any current level and higher RF energy exposure may activate over voltage safety elements, reducing RF energy delivery and overheating within the ORLab™ system's Stimulus Connection Box.

Subject to these requirements, the ORLab™ Stimulator is intended for use with the following equipment. The user should contact Micropace Pty Ltd for compatibility information prior to use of other equipment:

RF Ablation generators and ablation electrode catheters

The ORLab is tested for use with Atricure range of intra-operative RF Ablation products, including the Isolator ® System, consisting of the following products:

Isolator® System	Product Code
Isolator® pen, 19cm	MAX1 / MAX3
AtriCure® Source Switch Accessory	ASB1 / ASB3
AtriCure® Ablation and Sensing Unit	ASU2 / ASU3

ORLab's EPS320 Stimulus Generator Unit is compatible with a number of other commercially available RF generators and ablation catheters – contact Micropace Pty Ltd to for further information. (Refer also to "Warnings and Precautions" section below).

EP Recording equipment

Computerized EP Recording systems manufactured by Bard Electrophysiology (LabSystem™ Duo™ and LS Pro™) and GE/Prucka (CardioLab 4000, 7000) have been tested for use with the EPS320 Stimulus Generator Unit and are compatible with ORLab™.

Diagnostic pacing electrode catheters

ORLab's EPS320 Stimulus Generator Unit is compatible with most currently available legally marketed electrophysiological diagnostic electrode catheters, including those manufactured by Cordis Biosense Webster, Daig, CR Bard, Medtronic and EPT.

External ECG Monitor

ORLab requires an amplified surface ECG signal from an external source and is compatible with the ECG output of third party Patient Monitors such as the Phillips IntelliView Patient Monitor series and others having:

- 6.5mm Phone Socket with ECG signal on center pin
- Signal amplitude ±1V peak to peak full scale with source impedance < 3kOhms
- Amplification 20 to 1000

1.2 Important Patient Safety Warnings

Throughout this document, a **Warning** is intended to indicate a potential hazard or unsafe practice which, if not avoided, could result in death or serious personal injury, while a **Caution** conveys a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

1.2.1 General Warning

Warning: Stimulator must be used only under supervision by a cardiologist or surgeon.

- Cardiac Diagnostic Stimulators are used in medical procedures, during which intentional or unintentional life-threatening cardiac arrhythmias are likely to occur. To avoid death or injury to patient from arrhythmias, the Stimulator may be used on humans only by or under the direct supervision by a physician or surgeon familiar with electrophysiology and the operation of this Stimulator, and in an appropriate hospital facility.
- The supervising physician or surgeon must verify all Stimulator settings prior to commencement of pacing, with particular attention to any adaptively calculated S1 pacing interval settings.

Warning: Installation and use only by qualified personnel.

- In order to prevent electrocution hazards or impaired performance of the Stimulator from incorrect installation, only qualified personnel, such as representatives of Micropace Pty Ltd, its authorized distributor or hospital-appointed biomedical engineers, may carry out installation of the ORLab™ Stimulator and its connection to other equipment.
- In order to reduce operator errors, the installation, configuration and customer training should be performed in a manner, which allows optimal use of the stimulator by the user.

Warning: Stimulator is not a life support device – operator must have available backup temporary external pacemaker.

- To avoid injury to patient from bradycardia, operator must have available a backup temporary external pacemaker. The ORLab™ Stimulator System is a diagnostic tool for provocative electrophysiological testing of the human heart. The Stimulator System is not intended, designed or fit for the purpose of life support. Two levels of backup pacing for bradycardia are provided in case of failure of normal functioning of the stimulator and are for use in non-life-threatening bradycardia; in case of life-threatening bradycardia, pacing with a temporary external pacemaker must be established immediately.
- A backup temporary external pacemaker must be immediately available for use in case of the occurrence of a life-threatening bradycardia. It should preferably be connected directly to an intracardiac electrical catheter located in a ventricle, bypassing any switching apparatus in case of failure or inappropriate settings of such switching apparatus.

Warning: Stimulator must use isolated mains power supply only.

- To avoid electrocution hazards, all parts of the Stimulator system, including the computer, monitor, laser printer and the Stimulus Generator Unit must all be connected to the Mains Isolation Transformer and never directly to a mains outlet.
- To avoid electrocution hazards and prevent overloading the transformer, do not connect any other equipment to the supplied Mains isolation transformer.
- To avoid electrocution hazards due to mains cords bypassing the isolation transformer in the future, ensure that mains cords are retained in the isolation transformer outlets with the supplied screw-on Transformer Cord Retention Bracket and that power supply units next to the transformer are secure and access to be prevented by a screw-on cover supplied with the cart.

Warning: Connect Stimulator system only to legally marketed, mains-isolated electrical equipment.

- To avoid electrocution hazards, the stimulator system may be connected to other equipment provided the other equipment is also isolated from the mains. It must comply with electrical safety requirements of UL/IEC60601-1 or IEC60601-1-1 standards or equivalent as applicable, is legally marketed in the country and is CE marked for installations in the EU countries.
- Ensure that total earth leakage current of ORLab™ and any interconnected equipment under normal conditions does not exceed 500µA (300µA in USA).

Warning: Use Stimulator only in ventilated areas and away from flammable gasses.

- To avoid risk of explosion, the Stimulator should only be used in a ventilated area as gasses may be released during charging of backup battery, and should not be used in rooms with flammable anesthesia.

1.2.2 Warnings Specific to the ORLab™ Cardiac Stimulator

Warning: ORLab™ is not an ECG Monitor or Heart Rate meter and has no alarms – always monitor patient's vital signs with other equipment intended for such monitoring.

- The ORLab™ is a clinical diagnostic tool with only intermittent indirect access to patient electrocardiograms; it is not an ECG Monitor or Heart Rate meter for monitoring vital sign nor is it a life support device.
- When using the ORLab™, do not rely on the "Rate (/min)" displayed on the ORLab™ to represent patient's heart rate, as it may be set to count events other than QRS's. Always monitor the patient's ECG and Heart Rate with a separate approved ECG monitor / vital signs monitor.

Warning: ORLab™ may cause unexpected effects – always monitor patient's vital signs with other equipment intended for vital signs monitoring.

- The ORLab™ Stimulator may fail to stimulate or unintentionally stimulate the patient through software, hardware or human error. To avoid injury to patient from arrhythmias, monitor the function of Stimulator and patient's vital signs continuously while Stimulator is connected to the patient.
- In case of repeated recurrence of unexplained life-threatening arrhythmias despite cardioversion/defibrillation during the use of the Stimulator, disconnect the Stimulator from the patient by unplugging the green Pace Output plug on the front panel in case it has an occult malfunction causing recurrent micro-electrocution or recurrent DC current stimulation.

Warning: Patients with permanent or temporary pacemakers - ORLab™ ECG display and Rate measurement may be incorrect in the presence of pacing spikes.

- ORLab™ has no pacemaker spike detection or suppression. Pacemaker spikes may or may not be displayed and may or may not be counted in Rate measurement.

Warning: Burst Stimulation may induce Ventricular Fibrillation

- In order to prevent inadvertent induction of ventricular fibrillation, when applying Burst Stimulation, ensure stimulation electrode is not in contact with ventricular myocardium. In particular when pacing inferior parts of left or right atria, verify that no second ventricular electrogram is present in the atrial recordings prior to stimulation.

1.2.3 Warnings Related to the use of ORLab™ Stimulator with RF Ablation Equipment

Warning: Use Stimulator only with RF-filtered stimulus connection. (Micropace parts: MP3014).

- Use only supplied Stimulus Connection Box (MP3014), to connect Stimulator's stimulus output to patient circuits. The component contain RF suppression filters to prevent large RF energies from RF Ablation equipment not equipped with RF filters from reaching the Stimulator output circuits. Use of other, including custom made connectors may bypass RF filtering and potentially lead to repeated alarms and shutdowns of the Stimulator and possible induction of unintended life-threatening arrhythmias during delivery of RF ablation energy.
- The MP3014 component is over voltage protected by gas arrestors for differential voltages > 350VAC. Exposing these components to unfiltered RF ablation energies exceeding this limit (e.g. by direct connection to unfiltered RF Ablation energies > 150W or ablating into > 300 Ohm loads may cause reduction of RF energy available for ablation and overheating and a fire hazard within the MP3014 component.

Warning: Do not stimulate via ablation electrode during delivery of RF Ablation energy.

- To avoid possibility of unintended arrhythmia induction, do not stimulate myocardium via the ablation electrode during application of RF energy. Efficacy and potential for adverse effects of stimulation of heated myocardium in the process of ablation have not been established.

1.3 General Precautions in Handling Stimulator

Caution: Installation, Transport and Storage.

- To ensure reliable operation of the Stimulator, install the stimulator away from dust, excessive heat or humidity, direct sunlight and splashing liquids and in a well-ventilated place.
- To ensure that operator may readily see important error messages displayed during operation, install with the front panel of the Stimulus Generator Unit visible to the Operator, as important error messages may be displayed during operation.
- To avoid damage to the Stimulator, avoid exposure to chemical gases, excessive vibration, impact, temperatures above 60 Deg. Celsius or ambient air pressures equivalent to above 10,000m altitude during transport and handling.
- To ensure that backup battery remains fully charged, store system between uses with the Stimulus Generator Unit connected to mains power supply, switched on at the rear panel switch (green MAINS POWER LED should blink) and in Standby Mode to ensure that backup battery remains fully charged. The computer should be switched off.

Caution: Precautions prior to use.

- Ensure that all cables are properly installed and secured.
- Ensure that the mains power supply is isolated and that attached equipment is also electrically isolated and does not pose an electrical hazard.
- If the stimulator has been unused or may have been disconnected from mains power supply for more than 1 month, charge backup battery by leaving connected to the mains supply in Standby Mode overnight and check that Emergency Fixed Rate Pacing and the stimulator generally functions correctly.

- Do not use the stimulator if any component appears damaged, computer appears to start up abnormally, or error messages appear on the computer screen or Stimulator front panel. If in doubt, contact the Distributor or Micropace directly.
- Ensure that the Operator is trained thoroughly on how to switch the Stimulator to Backup Manual mode or Emergency Fixed Rate Pacing modes.
- To prevent ORLab™ software malfunction, do not install other software.

Caution: Precautions during use.

- The entire EPS320-ORLab™ may be used in the Patient Environment.
- Observe the stimulator and patients at all times for abnormal function and rectify any problem promptly or disconnect the patient from the stimulator (by unplugging the green plug from the green PACE OUTPUT socket on the front panel).
- Do not use the Stimulator and disconnect it from the patient if it repeatedly switches to Backup Manual mode and displays error messages on the front panel. Contact your Micropace Distributor.
- To ensure reliable stimulus capture, set stimulation current according to capture threshold whenever changing stimulation site or catheter. Two times threshold is usually used.
- Use of excessive stimulation currents may induce fibrillation and produce misleading results in ventricular stimulation studies.
- To reduce chance of accidentally inducing ventricular fibrillation, ensure reliable ECG sensing and use QRS SYNC function to avoid stimulating in the vulnerable diastolic period where appropriate.
- Line isolation monitor transients may resemble actual cardiac waveforms and thus make Rate measurements incorrect. Such transients may be minimized by proper grounding of ORLab™ and following directions for the connection of ORLab™ to other equipment.
- ORLab™ indicates inoperative state in one of two ways:

  (i) Error message or ‘freeze’ of or loss of display on computer screen followed 7 seconds later with Stimulus Generator Unit (SGU) adopting Backup Manual mode, displaying ‘600’ and ‘5.0’ on its front display. You may now operate the SGU by the buttons on its front panel to urgently pace the patient if required. You may also power off and on the computer.

  (ii) Error message on front of Stimulus Generator Unit, in which case, if you need urgent pacing, you may move green Stimulus Output plug to the Emergency Fixed Rate Output which will pace Chan 2 (Ventricle) only. ORLab™ is not a life support device, connect patient to a temporary pacemaker box as soon as possible. ORLab™ should be serviced before further use.

Caution: Precautions between uses.

- The ORLab™ Stimulator should be connected to external power; its Power switched to the On position at the rear panel switch and in the Standby Mode while not in use to ensure that backup battery remains fully charged.
- The Stimulator should be maintained according to “Maintenance” section of this manual.

1.4 Adverse Events[1]

The ORLab™ produces standard cardiac stimulation outputs similar to other existing programmable cardiac stimulators in use for the past 30 years; there are no known adverse effects from short term diagnostic use of such stimulation when applied correctly. Following is a list of potential adverse events from Stimulator device malfunction or human error (in alphabetical order):

- Arrhythmia
- Death
- Explosion or fire
- Myocardial injury
- Operator electrocution

Refer to above Warnings and Precautions.

1.4.1 Observed Adverse Events

The ORLab™ produces standard cardiac stimulation outputs similar to other existing programmable cardiac stimulators in use for the past 30 years. The standard pulse output characteristics are well defined in standard Electrophysiology texts and the application, safety and clinical efficacy of this group of devices is well established in the medical field and in one recent review by McLaughlin et al ["Review of seven cardiac electrophysiology stimulators", by N.B.McLaughlin, C.J.Griffiths, R.W.F.Cambell et al in Physiol.Meas., 14 (1993) 57-69].

Report of adverse events related to EPS320 arises from the following clinical experience with the product subject to product vigilance (device exposure estimated by adopting an estimate of 14 patients per stimulator per month of use, each patient exposed for an estimated mean time of 2.5 hours)

Clinical use of the device in its evolving form since January 1998, evaluated in October 1999 by a survey of 6 clinicians using 6 Stimulators with an accrued clinical experience with the product on more than 1600 patients

- A prospective field trial of safety and efficacy of the EPS320 performed in May to July 1999 concurrently at 4 hospitals in Sydney, involving 6 Stimulators / cardiologist users and a total of 23 patients.
- Clinical use of the EPS320 in Australia and Southeast Asia from July 1999 to October 2001, involving 22 Stimulators and an estimated 7400 patients.
- Clinical use of the EPS320 in EC countries from January 2001 to October 2001, consisting of 17 Stimulators accumulating clinical exposure to an estimated 2400 patients.

The EPS320 Stimulator has thus been used on an estimated total of 10,000 patients, approximately half using the current firmware version, leading to an estimated device exposure of 25,000 hours.

No deaths or injuries related to the use of the EPS320 Stimulator have been reported during the device exposure.

Two adverse events were reported, both due to device interaction with an RF Ablation Generator. They were non-sustained Ventricular arrhythmias arising when operators simultaneously paced and delivered RF ablation energy through the same ablation electrode; the EPS320 Stimulator detected the interaction and shut down in both cases. Device interaction has been eliminated in the field by the issue of a Safety Alert warning against this application and the addition of RF filters to Stimulator's Stimulus Connection Box to isolate Stimulator from RF signals.

[1] Sections 1.4 – 1.8 for US Market only

1.5 Potential Adverse Events

Following is a list of potential adverse events which could be directly associated with diagnostic cardiac stimulation using the ORLab™ during electrophysiological studies (alphabetical order):

Bradycardia or asystole

- Should a patient develop bradycardia or asystole during the use of the Stimulator, failure to promptly backup pace the patient may lead to hypotensive injury within seconds to minutes. Such arrhythmia may typically occur (i) in patients with atrio-ventricular conduction defects, (ii) during placement of intra-cardiac electrode catheters, (iii) after cardioversion/defibrillation or (iv) during RF ablation.
- The Stimulator may fail to normally deliver stimuli due to (i) power failure or power interruption, (ii) failure of PC, (iii) loss of communication between PC and Stimulus Generator Unit (SGU), e.g. due to lead disconnection or (iv) failure of SGU itself due to spontaneous fault or damage from external events such as defibrillation of RF ablation energies.
- To avoid patient injury, the user may use the battery powered Backup Manual Pace mode in case of power failure, failure of PC or the communication link, and the Emergency Fixed Pacing mode in case of failure of normal operation of the SGU. The ORLab™ Stimulator is not a life-support device; these functions are for use in non-life-threatening bradycardia or until external temporary pacing is established in case of asystole. Refer to “The EPS320 Stimulus Generator Unit” section below for instructions on the use of these features.
- DC voltages greater than 5000V or RF voltages greater than 350V pp applied to Stimulator outputs may cause circuit failure; the Stimulator issues a range of alarms in case of failure of output circuits – see Section “Hardware Error Messages on the Stimulus Generator Unit”

Explosion or fire

- Explosion could arise from accumulation and ignition of explosive gasses vented from charging of the backup battery within the Stimulator. Use Stimulator only in well-ventilated areas.
- Explosion could also arise from electrical sparks within the Stimulator igniting explosive anesthetic gasses in the operating room. Do not use Stimulator in the presence of volatile anesthetic gasses.
- Continuous RF voltages greater than 350V pp applied to Stimulator outputs in contravention of labeling may cause overheating of the Stimulus Connection Box and possibly cause a fire hazard. Similar hazards would probably be present in other equipment with over voltage protection. Special care will be required should RF generators capable of delivering such voltages (corresponding to in excess of 150W into 300 Ohm load) become available.

Myocardial injury

- Excessive current flows through intra-cardiac electrodes, such as due to failure of Stimulator output circuit causing excessive stimulation currents and inadvertent shunting of defibrillation or RF ablation energies through a malfunctioning Stimulator or equipment attached to its outputs could theoretically cause localized myocardial damage at the pacing electrode.
- In order to minimize risk of myocardial injury, connect ORLab™ Stimulator stimulation outputs only to legally marketed medical equipment compliant with UL/IEC60601-1 and IEC60601-1-1, and if error messages appear on the SGU, consult the section “Hardware Error Messages on the Stimulus Generator Unit.” prior to using the Stimulator again.

Operator electrocution

- The ORLab™ Stimulator auxiliary signal input/output ports and RS232 communications port are optically isolated from patient circuits, but connect directly to Stimulator signal ground plane, in accordance with UL/IEC60601-1. Connection of these ports to equipment without appropriate mains isolation or protective grounding may cause electrocution of the operator by mains-derived AC current in case of malfunction in the connected equipment.
- In order to minimize risk of electrocution to the operator, connect ORLab™ Stimulator input/output ports only to legally marketed medical equipment, isolated from mains power and compliant with UL/IEC60601-1 and IEC60601-1-1.

Ventricular tachycardia or fibrillation

- The ORLab™ Stimulator may be used to intentionally induce ventricular or atrial arrhythmias including ventricular tachycardia and fibrillation. Causes of inadvertent induction of such arrhythmias includes operator error, Stimulator malfunction and device interactions:

  (i) Myocardial stimulation with DC current.
  Myocardial stimulation with DC current is likely to cause arrhythmias, including intractable ventricular fibrillation (if operator is unaware of the fault and does not remove the source from the patient, ventricular fibrillation may repeatedly recur after defibrillation, possibly leading to patient death). DC current flow in the stimulation circuit loop may potentially be caused by Stimulator output circuit failure, failure in other third party equipment inserted in the stimulation circuit loop or device interaction between interconnected equipment. Should the ORLab™ detect such a condition a DC-ERROR alarm is issued, (_,d,c,_,E,r,r displayed on SGU front panel and DC-ERROR alarm message on the computer), followed by a safe state shut down of the Stimulator. Refer to section “Hardware Error Messages on the Stimulus Generator Unit” below for instructions in this case. Regardless of Stimulator alarm state, recurrent unexplained ventricular fibrillation should prompt user to immediately disconnect the patient from the stimulation circuit, preferably at the intracardiac electrode catheter connectors.

  (ii) Intended cardiac stimulation in the vulnerable diastolic cardiac period
  User should ensure that ECG sensing by the Stimulator is reliable and always use the QRS Sync function to avoid stimulating in the vulnerable diastolic period, where appropriate. External amplified ECG signal is the recommended source of ECG, however, where external ECG source is not available or unreliable, the ORLab™ may be configured to sense intra-cardiac ECG from either of the stimulation output channels.

  (iii) Inappropriately rapid cardiac stimulation
  Cardiac stimulation at rapid intervals, typically less than 300 ms, may cause undesirable arrhythmias including ventricular fibrillation. Inadvertent rapid stimulation may occur either through user error, inappropriate Stimulator software safety parameter configuration or Stimulator hardware or software malfunction. The Stimulator’s SGU monitors for un-programmed rapid stimulation and if detected, issues a Rate Error alarm, followed by a shut down safety state. Monitor the Stimulator function, patient’s ECG and observe the patient continuously for unexpected behavior whenever patient is connected to the Stimulator; disconnect the patient from the Stimulator and do not use if abnormal stimulation is observed.

  (iv) Un-programmed isolated stimulation pulses
  Unintended cardiac stimulation with isolated stimulation pulses may cause undesirable arrhythmias including ventricular fibrillation. Isolated stimulation pulses may potentially occur due to Stimulator hardware or software malfunction. The Stimulator’s SGU monitor detects un-programmed stimulus pulses occurring within 300 ms of another stimulus pulse and issues a Rate Error alarm, followed by a shut down safety state. Monitor the Stimulator function, patient’s ECG and observe the patient continuously for unexpected behavior whenever patient is connected to the Stimulator; disconnect the patient from the Stimulator and do not use if abnormal stimulation is observed.

(v) Mains derived AC current microshock
Mains derived AC leakage currents to ground may cause patient microshock leading to arrhythmias, including intractable ventricular fibrillation. AC leakage currents may potentially arise from a malfunction in the ORLab™ Stimulator or connected third party equipment if the mains power supply is not isolated in all interconnected equipment. Ensure that the ORLab™ Stimulator system, including the PC and all connected third party equipment is connected only to isolated mains power supply.

1.6 Summary of ORLab's EPS320 Stimulus Generator Unit field trial

Introduction:

EPS320 Stimulus Generator Unit used in the ORLab's configured system was validated in the clinical setting by a field trial of a related configuration, model EPS320B Cardiac Stimulator, using the same generator unit and similar computer interface architecture, and by subsequent field clinical experience with this generator unit from 800 products placed into the market since 2001. The ORLab's integration of this generator unit with a new computer graphical interface and a printer was verified by laboratory testing to perform according to specifications and validated by one user expert in the field of clinical electrophysiology.

The field validation trial of the earlier EPS320B stimulator was performed by a sample of end-users while subjected to typical sources of potential interference, such as Radio Frequency (RF) ablation energies and DC cardioversion. Validation end points were the absence of adverse events during the procedure, demonstration of adequate pacing in all protocols for the duration of typical Electrophysiological (EP) study and RF ablation procedure without interruption, adequate sensing of QRS, subjective scoring of fitness for purpose by user and freedom from error states.

Patients studied:

23 clinically indicated EP studies with or without RF ablations in 23 patients in routine clinical settings. A total of 6 operators used the EPS320 Cardiac Stimulator in 4 different hospitals.

Methods:

The protocol consisted of the collection of data on stimulator clinical performance by a trained observer during routine clinically indicated EP studies by cardiologists. Sequential patients were chosen and no change to the routine clinical management of patients was made.

Device performance was assessed qualitatively with defined pass criteria for each case study and defined criteria for overall device pass or fail for each application.

Results:

Data was collected from 23 EP studies, consisting of 10 cases of RF ablation of supraventricular tachycardia(SVT), 4 studies of ventricular tachycardia (VT) , 3 syncope studies and 6 other study types. The stimulator was used during delivery of RF ablation energies in 14 of the cases and during DC cardioversion of patient on 6 occasions in 4 patients. Results are shown in Table 1 below. No hazardous events or stimulator failures were observed; Stimulator functioned as per specification at all times in all cases.

Conclusions:

The EPS320 Cardiac Stimulator:

- Performs within acceptable safety parameters at all times.
- Performs substantially to the system requirements set out for the device and appears to satisfy Electrophysiologist's clinical requirements.

PARAMETER	TOTAL/ MAX	PASS
Nominal Protocol Stimulator performance (all must pass)		**23/23**
All programmed pacing stimuli are delivered (all = pass)	-	23/23
Adequate capture achieved (all expected = pass)	-	23/23
Adequate sensing: 4:>90%, 3:70-90%, 2:50–70%, 1: <50% (>70%=Pass)	74/105	22/22
Upper and lower limits of variables satisfactory for clinical purpose? (Ask clinician)	-	23/23
Did Sync-to-QRS function correctly- pacing started on all first (detected) QRS?	-	8/8
Performance during tachycardia (all must pass)		
Adequate sensing4:>90%, 3:70-90%, 2:50–70%, 1:<50% (>70%=Pass)	53/85	18/18
Performance during RF ablation (all must pass)		
No Stimulator Error during ablation	14/14[1]	14/14
Operator able to recover stimulator from error	-	-
Performance during defibrillation (all must pass)		
Number of defibrillations during study;	6	-
Record of any malfunction (no., none = pass)	0	6/6
Failure modes (all must pass)		
Did error codes appear on stimulator Unit? (No=Pass)	0	23/23
Loss of communication between PC and Unit occurred? (No=Pass).	0	23/23
If communication lost, was it re-established easily? (Yes=Pass)	0	23/23
Record of any computer freeze or unexpected behavior as well as any display anomalies, (None = pass).	0	23/23
Test of Backup Manual stimulation (all must pass)		
Did Interval and Current adjustments work and pacing stimuli work? (Yes= pass)	6	6/6
Did all stimuli capture patient; (all = pass)	6	6/6
Emergency fixed pace operation worked (all stimuli issued)	6	6/6
User performance Score (5=very good, 4=good, 3=adequate, 2=poor, 1-unsatisfactory)		
User-friendliness of computer user interface (self-evident menus/operation)	71/80	16/16
Ergonomic (speed, ease, minimum number of steps) of operation.	70/80	16/16
Overall Safety of operation.	72/80	16/16
Reliability of operation, lack of breakdowns, delays.	75/80	16/16
Fit for purpose of EPS Stimulation (essential features)	75/80	16/16
Comprehensiveness of features within system (all desired features)	73/80	16/16
Flexibility of use (adaptability to non-standard/new uses)	60/70	13/13

Table 1 Results for individual measured parameters

Notes:

[1] During one study, the Stimulator entered Fail Safe operation mode due to a false alarm without causing hazard to the patient after the pacing electrode inadvertently directly contacted the RF Ablation electrode during application of RF energy (the Stimulator alarm was subsequently modified, validated and appropriately labelled as per current labelling).

1.7 Individualization of treatment & Patient Counseling Information

- Pacing threshold in each chamber studied should be established prior to stimulation and stimulation current should generally be set at twice the pacing threshold or 1mA, whichever is greater. Pacing thresholds may differ with different catheter positions and presence of myocardial scarring.

- To our knowledge, the ORLab™ Stimulator requires no specific counseling in addition to standard patient consent by the clinician for the overall EP Study or RF Ablation procedure during which it is to be used.

1.8 References

(1) AHA Medical/Scientific Statement: ACC/AHA Guidelines for Clinical Intracardiac Electrophysiological and Catheter Ablation Procedures. Circulation. 1995;92:673-691

(2) Adams, D.E: Setting Up the Laboratory for Ablation. Catheter Ablation of Arrhythmias. D. Zipes ed. Futura Publishing Company, Inc., Armonk, New York. 1994: 89-90.

(3) Josephson, ME: Clinical Cardiac Electrophysiology: Techniques and interpretations. 2nd Edition. Lee & Febiger, Pennsylvania, 1993:pp10, 67.

(4) McLaughlin, NB Griffiths CJ, Campbell RWF and Murray A. Review of Seven cardiac Electrophysiology stimulators. Physiol.Meas. 14 (1993) 57-69.

2. DEVICE RATINGS, CLASSIFICATION AND CERTIFICATION

CE Mark Compliance

The ORLab™ Cardiac stimulator system, is compliant with the following EEC directives:

- 89/336/EEC & 92/31/EEC (EMC Directives)
- 73/23/EEC (Low Voltage Directive)
- 93/42/EEC (Medical Device Directive)
- 93/68/EEC (CE Marking Directive)

CE 0120 Issuing Notified Body – SGS.

Compliance Testing was carried out and coordinated by the following Certified Bodies:

- EMC Technologies, Castle Hill, Australia
- TCA - Testing and Certification Australia, Chatswood, Australia

The ORLAB™ Cardiac stimulator classification:

- TGA, Rule 4.3 Classification
  Class IIb
- Medical Devices Directives (93/42/EEC & 93/68/EEC), Rule 10 classification:
  Class IIb medical device
- IEC60601-1 electrical device classification:
  Class II (mains-isolated by approved external isolation transformer), IPX0, Type CF
- FDA Medical Device Level of Concern
  Level II
- Health Canada Medical Device Classification, Rule 10(2)
  Class III

The ORLab™ Cardiac stimulator system Power rating:

- 220-240VAC 50-60Hz, 4.1A max (while printing), 1.5A (not printing)
- 110-120VAC 60Hz, 8.6A max (while printing), 2.2A (not printing)

Identification of technical standards with which compliance is claimed:

- ISO 13485:2003 Quality management systems - Medical devices - System requirements for regulatory purposes
- IEC60601-1 Medical Equipment – Part 1: General requirements for safety.
- IEC60601-1-2 Medical Equipment – Part 1: General requirements for safety. Collateral Standard: Electromagnetic compatibility – Requirements and tests
- ANSI/AAMI EC13:2002 Cardiac monitors, heart rate meters, and alarms (relevant clauses only).
- ANSI/AAMI/IEC 62304:2006 Medical Device Software – Software Life Cycle Processes.

3. COPYRIGHT, WARRANTY AND DISCLAIMER NOTICE

Copyright and Trademark Notice

Copyright © 1994-2008 by Micropace Pty Ltd.
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All rights reserved, Printed in Australia

Datalight and *ROM-DOS* are registered trademarks of Datalight, Inc. Copyright 1989-2007 Datalight, Inc., All Rights Reserved.

The ORLab™ Cardiac Stimulator System is protected under applicable copyright laws. Purchase and use of this System is subject to the following agreements:

License Agreement

You may:

(i) use this program on only one computer at a time;

(ii) make a copy solely for the purpose of backup.

You may not:

(i) distribute copies of this program or documentation to others;

(ii) rent, lease or grant sublicenses to the program to others without prior consent from Micropace Pty Ltd.

Your license to use this program will terminate automatically if you fail to comply with the terms of this Agreement. A full copy of the license agreement can be found in the software.

Limited Warranty

Micropace warrants that, for a period of one year from the date of installation of the Product, the Custom Hardware will under usual use be free from defects in materials and workmanship.

The Software will, when properly used in accordance with this license, operate in accordance with its applicable specifications published by Micropace, be free of material defects and be fit for the purpose intended by Micropace.

Micropace shall have no obligation to make repairs to, or replace, Products which are damaged by normal wear and tear, or which result from (i) catastrophe, fault or negligence of a person other than Micropace, (ii) improper or unauthorised repair, or (iii) causes external to the Products, including, but not limited to, power surges, extreme environmental conditions outside of specifications or mishandling, such as spillage of liquids within the Products. All claims for warranty services must be directed to your authorised Micropace distributor.

Except for the above express limited warranties, and subject to law, Micropace makes, and you receive, no warranties, express, implied, statutory, or in any communication with you; and Micropace specifically disclaims any other warranty including the implied warranty of merchantability or fitness for a particular purpose. Micropace does not warrant any of the third party hardware or that the operation of the product will be completely free from minor software or hardware inconsistencies.

The Stimulator must only be used by appropriately qualified and experienced personnel, in appropriate facilities and in conjunction with appropriate safety equipment as described in section “Important patient safety warnings” above. Micropace accepts no responsibility for any consequences arising out of the use of the Stimulator outside of these restrictions. The Operator should verify for him / herself that each function of the Stimulator performs to the Operator’s expectation prior to use of the Stimulator on patients.

4. EXPLANATION OF SYMBOLS

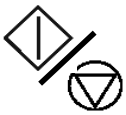
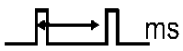
Explanation of symbols. Table 2 below lists explanations of symbols displayed on various parts of the Stimulator system.

Symbol	Name	Meaning	Location
	Attention	Explosion Hazard. Not for use in the presence of flammable gasses such as some anesthetic mixtures. Do not expose to liquids. No user-serviceable parts inside. Refer Service to qualified service personnel.	Next to POWER ON/OFF switch on rear panel of Stimulus Generator Unit
	Attention	In order to avoid patient electrocution, connect only to Micropace supplied power supply unit (PSU), which must be connected only to transformer isolated mains power outlet.	Next to POWER INPUT on rear panel of Stimulus Generator Unit
	Attention	Connect only to Micropace supplied parts.	Next to AUXILIARY PORT on rear panel of Stimulus Generator Unit
	Attention	Cardiac pacing output. Read Important Patient Safety Warnings and General Precautions in Handling Stimulator section at the front of this document.	1. Pace Output Socket. 2. Emergency Fixed Rate Pacing output socket.
	CF Defibrillator	Type CF defibrillator protected equipment.	Front of Stimulus Generator Unit: 1. Pace Output Socket. 2. Emergency Fixed Rate Pacing output socket.
	CE Marking & Notified Body Identification	This item is in compliance with the requirements of the European Union EMC, Low Voltage and MD directives and is labeled in accordance with the requirements of these directives.	1. Side of Stimulus Generator Unit.
	CE Marking	The commercially available Isolation transformer and Low voltage transformer supplied with each system fully comply with EMC and Safety Standards	1 Isolation Transformer. 2 Low voltage Transformer
	Equipoten-tiality	System central grounding terminal.	Next to the earthing terminal on Isolation Transformer

Symbol	Name	Meaning	Location
0	Power OFF	Device is switched OFF; battery is NOT charging. Note that the MAINS light glows yellow to indicate that power is available to the device.	Next to **POWER** switch on rear panel of Stimulus Generator Unit
I	Power ON	Device is switched ON and battery is charging.	Next to **POWER** switch on rear panel of Stimulus Generator Unit
	Increase / Decrease	Increase / Decrease adjacent Interval or Current parameter.	On the front of Stimulus Generator Unit next to Interval Current displays
+	Positive Output	Positive stimulus output. Defibrillator CF Protected part	On Stimulus Connection Box
—	Negative Output	Negative stimulus output, Defibrillator CF Protected part	On Stimulus Connection Box
WARNING	Warning	Not Suitable for direct connection to RF Ablation Power > 150W into 300 Ohms	On Stimulus Connection Box

Table 2 Explanation of symbols

Table 3 below lists explanations of symbols displayed only on the ORLab™ SGU.

Symbol	Name	Meaning	Location
	Mains Power	**No light:** No external power to SGU. **Orange Light:** Connected to Mains Power, but SGU switched off at Power Switch at rear. Battery is not charging. **Green Light**: Connected to Mains Power and SGU switched on – in Manual Backup or PC Pace Control modes. Battery is charging. **Green Light Flashing:** Connected to Mains Power and SGU in Standby state. Battery is charging.	Left Front Panel of Stimulus Generator Unit
	Battery Power	SGU is powered by Battery.	
	Battery Low	Battery is nearly discharged. Connect to mains power to continue use of SGU.	
	PC Pace Control	SGU is under control of Computer. Use touch screen, if fitted, to control pacing.	
	Pace On/Off	Press to toggle start / stop pacing.	Left centre Front Panel of Stimulus Generator Unit
	Backup / Standby	Press to toggle between Backup Manual Pace Control and Standby.	
	Pace Interval	Basic pacing interval in ms.	
	Current	Current amplitude of stimulus.	
	Ch1 (Atrium)	Green flash: Stimulus into Channel 1, usually located in Atrium.	Right centre Front Panel of Stimulus Generator Unit
	Ch2 (Ventic)	Green flash: Stimulus into Channel 2, usually located in Ventricle.	
	Check Lead	Stimulus current not able to be delivered because of a break in the electrical lead / circuit.	

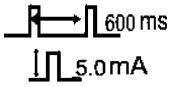
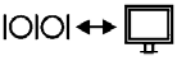
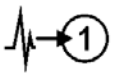
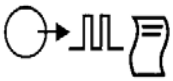
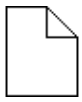
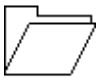
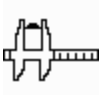
Symbol	Name	Meaning	Location
	Plug in to pace Ventricle Ch2 100ppm @5mA	Plug green patient connection cable into this socket to immediately pace Ventricle Ch2 at 100ppm @ 5mA. Note: Ch1 Atrium is not paced.	Right Front Panel of Stimulus Generator Unit
	Pace V Ch2	Green flash: Stimulus on Channel 2, usually located in Ventricle.	
	Battery	Emergency Fixed Pace Output enabled and powered from a battery with adequate charge.	
	DC Power	Direct Current power input, voltage and current consumption as specified.	Rear panel of Stimulus Generator Unit
	Computer Link Port	Port for connection to controller computer; use Micropace cable only.	
	Auxiliary Port	Port for connection to Stimulus Multiplexer Box; use Micropace cables only.	
	ECG-1 Input ECG-2 Input	High Level ECG input, 1V peak-to-peak.	
	Sync-1 Output	Digital 0-5V sync output for triggering recorders	

Table 3 Explanation of symbols – specific to the ORLab™ SGU

Explanation of symbols. Table 4 below lists explanations of symbols displayed within the ORLab's software application.

Software Icon	Icon Descrip-tion	Name	Location	Meaning
	Paper Sheet	New Session	Current Study page	Start new study or session. Erases any stored files from prior study, stamps new study with current date, time, surgeon and unique i.d. No.
	Floppy Disk	Save Data Snapshot	Sense/Pace, Burst Stim, Review pages	Save current ECG & Event data snapshot of up to the last 80 sec to file, naming it sequentially.
	Camera	Pause/ Review Snapshot	Sense/Pace, Burst Stim, Review pages	Temporarily saves and displays up to 80 seconds of preceding ECG/Event data and displays in Review page for review, measurements and printing. When pressed from Review page, updates displayed data with live data.
	Folder	Open File	Sense Pace, Burst Stim, Review pages	Open file browser
	Printer	Print Screen	Sense Pace, Burst Stim, Review pages	Print current ECG/Event screen to printer
	Multi_Prin ter	Print Buffer	Review Page	Print current ECG/Event buffer onto multiple pages on printer.
	Caliper	ECG Caliper	Review Page	Screen calipers for measuring time intervals on the screen
	Down Arrow	Rate low	In Rate /min Display	Rate lower than 20 /min
	Up Arrow	Rate High	In Rate /min Display	Rate above 600 /min
	Spanner	Aux Pace Control	Pace Sense, Burst Stim pages	Auxiliary Pace Control for the pacing protocol from which called.
	Waveform threshold	QRS Threshold	Pace Sense, Burst Stim pages	Adjust QRS bidirectional peak detector threshold
	Scale		Pace Sense, Burst Stim pages	Replaces QRS Threshold icon when latter is pressed. Returns to ECG gain adjustment controls.

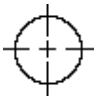
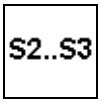
Software Icon	Icon Descrip-tion	Name	Location	Meaning
	Factory	Reset to Factory Defaults	Aux Pace Control page, Num Keypad	Reset values to Factory Defaults
	Right arrow	Interactive Configurati on	Aux Pace Control page	Sets interactively your preferred default values for ECG and pacing parameters
	Rubbish Bin	Discard	Aux Pace Control page	Discard any changes made to values
	Question Mark	Help	Any Page	Display Help text
	Left Arrow	Return to Previous	Any page	Return to previous page or menu
	Righht Arrow	Proceed to next	Any page	Proceed to next page
	Red Cross	Emerg-ency Pace	All pages	Emergency pacing. Starts pacing into both channels immediately at 80ppm with pulses of 5mA amplitude and 2ms pulse width.
	X	Exit	Any Page	Exit page / menu
	Standby	Standby	Current Study Page	Exit ORLab™ to Standby Mode. Press screen to re-activate, or switch off/on power.
	Cross Hairs	Calibrate Touch Screen	Service Page (from Current Study Page)	Calibrate touch screen.
	S2 to S3	EP Stimulator	Service Page (from Current Study Page)	For pacing extra-stimuli and full Electrophysiology Stimulator functions, launches EPS320 stimulator software. NB this mode has one ECG trace and no ECG storage or printing functionality. Quitting EPS320 returns to normal ORLab™ mode.

Table 4 Explanation of symbols in ORLab™ Software

5. INSTALLATION INSTRUCTIONS

5.1 Technical Description

ORLab™ is a diagnostic computerized cardiac stimulator and a recorder. The device consists of the microprocessor controlled EPS320 two channel stimulus generator unit (SGU) capable of cardiac pacing under control from its front panel, however normally controlled via a serial communication channel from a personal computer with a touch screen user graphical interface. The interface displays 3 ECG traces, two intra-cardiac electrograms from each of the pacing channels and one surface ECG obtained via a high level ECG signal derived from a third party ECG monitor. The system can temporarily store and print electrograms on a laser printer.

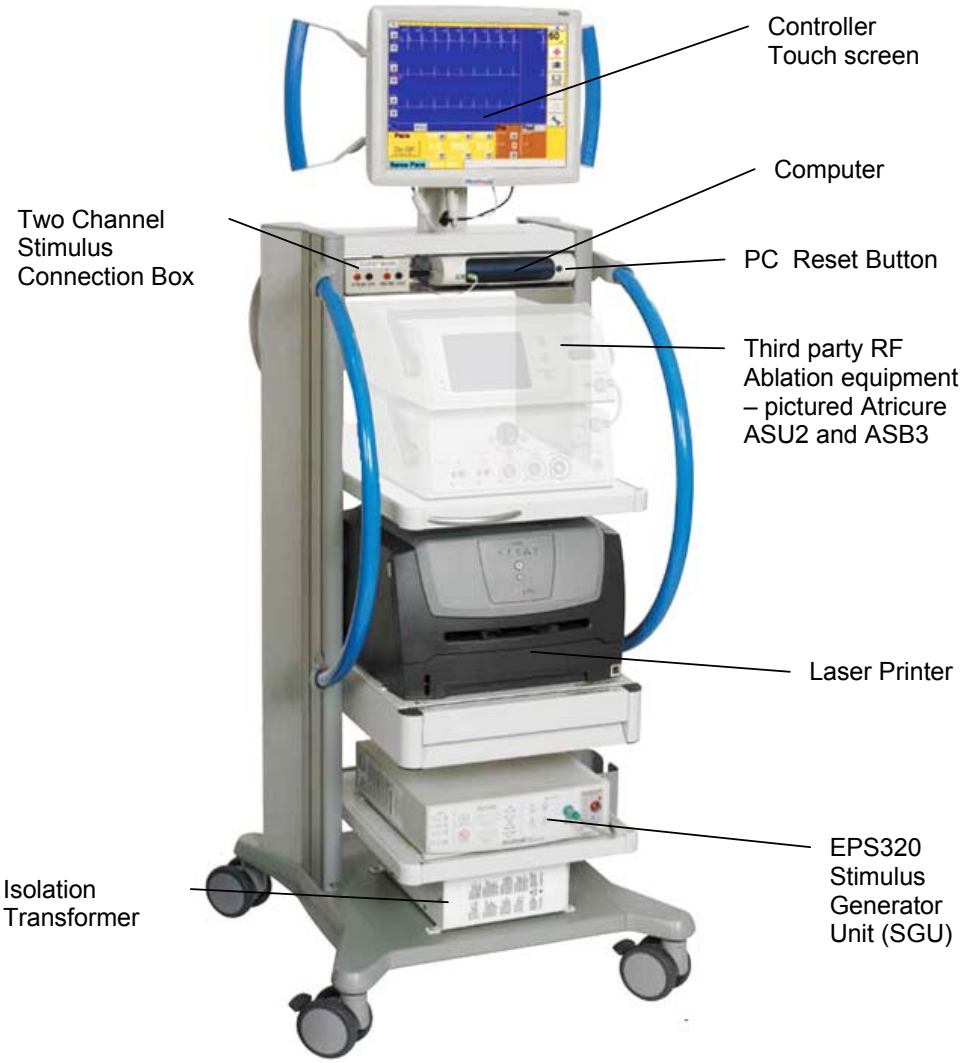


Figure 1 ORLab™ EP Stimulator / Recorder System (NB: pictured with wheeled cart and ablation equipment supplied separately from Atricure Inc.)

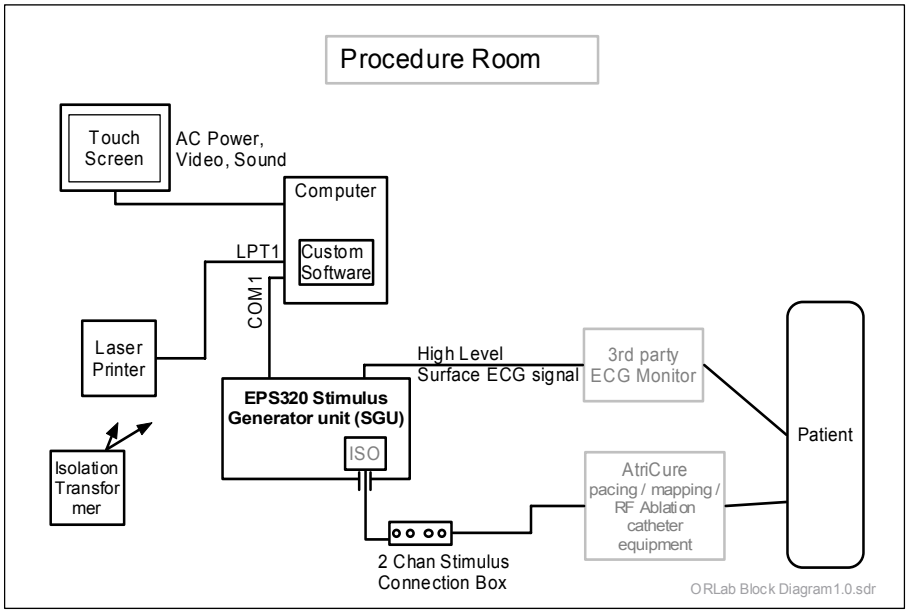


Figure 2 ORLab™ components and Schematic

5.2 Who may install the ORLab™

Installation must be performed only by qualified personnel, such as representatives of Micropace Pty Ltd, representatives of its authorized distributor listed at the front of this manual or hospital-appointed biomedical engineers.

5.3 How ORLab™ supplied

The ORLab™ is shipped in five cartons as described below. Cabling is supplied separately in the Power and Cabling Kit (Cart Cable Package) pre-wired into the ORLab™ System Cart by the Cart manufacturer prior to delivery to customer.

1. STIMULATOR & PC CARTON MP3192		
Item	**Part No.**	**Qty**
Stimulus Generator Unit (SGU)	MP3008	1
Bona Light PC installed with ORLab™ software	MP3197	1
Accessories Box	MP3196	1
Stimulus Connection Box	MP3014	1
Accessories Booklet	MP3318	1
External ECG Cable with 6.5 mm phone connectors	MP3313	1
Installation kit, Incl. Test LED	MP3304	1
Test LED, Yellow/Red	MP3058	1
Documentation:	-	
ORLab™ User Instruction Manual	MP3309	1
ORLab™ Quick Installation Guide	MP3310	1
Touch Screen Quick User Guide	MP3136	1
Manufacturer's Test Certificate	-	1

2. ELO Touch Screen Carton MP3193		
Item	**Part No.**	**Qty**
ELO Touch Screen and Accessories:	MP3114	1
Washer, Flat, M3, ZINC	MC0009	2
3mm screws, 8mm length	MC0007	2
Touch Screen DC plug cover bracket	MC0537	1
ORLab™ Touch Screen Instruction Leaflet	MP3199	1

3. Isolation Transformer Carton MP3195US / EU		
Item	**Part No.**	**Qty**
Isolation Transformer, 1000VA 9xIEC outlets, UL/IEC60601-1	MP3301EU/US	1
Isolation Transformer Instructions Leaflet	MP3312	1
Mains Power Cable, Wall socket to Cart (**EU ONLY**)	MP3317EU	1
Isolated Mains Power Lead IEC3 to 2 Pin (**EU ONLY**)	MP3148EU	1

4. Printer Carton MP3194US / EU		
Item	**Part No.**	**Qty**
Lexmark E250D Laser Printer	MP3302EU/US	1
Printer Instructions Leaflet	MP3311	1
EU ONLY Localization Kit	MP3329EU	1
Electronic copy of User Instruction Manuals	MP3330EU	1
Language support pack	MP3149	1
Dutch label set	N/A	1

5. Power and Cabling Kit (Cart Cable Package) MP3315		
Item	**Part No.**	**Qty**
Power Supply for SGU 100-240VAC to 15VDC	MP3074	1
Serial Boost RS232 Cable	MP3033A	1
Isolated Mains Power Lead IEC3 to 2 Pin, US Style	MP3148US	1
Power Supply for Bona PC 100-240VAC to 12VDC	MP3335	1
Power Supply for ELO Touch Screen, 100-240VAC to 12VDC	MP3300	1
Universal Isolated Mains Power Lead IEC3 to 3 Pin	MP3030	1
Universal Isolated Mains Power Lead IEC3 to 3 Pin	MP3142	2
Printer Data cable	MP3303	1
Serial cable for ELO Touch Screen	MP3114-1	1
Speaker cable for ELO Touch Screen	MP3114-2	1
VGA Video cable for ELO Touch Screen	MP3114-3	1
Mains Power Cable, Wall socket to Cart, US Style	MP3317US	1
Metal Bracket for Transformer to retain cables	MC0533	1

NB: These components may be pre-wired in a trolley.

5.4 Stimulator Options

No optional accessories are available for this product.

5.5 Connect System Components

Read manual. Read this manual completely before assembling the system, particularly the Safety Warnings and Precautions above.

Reqired Tools. You will need (i) screwdriver, medium size Philips head, (ii) ECG simulator for testing.

Quick Installation Guide diagram below. Refer to Quick Installation Guide A3 diagram supplied with the system, also repoduced in A4 format below.

Assemble ORLab™ components. Place ORLab™ components securely on shelves or within a trolley in a clean, dry environment with adequate ventillation around each component. Where ORLab™ is to be installed into a mobile trolley, such as the one supplied by Atricure Inc. illustrated in Figure 1, place the heavy isolation transformer on the bottom shelf, Stimulus Generator Unit on the second shelf just above it, the laser printer on the third shelf, AtriCure® ASU2 and ASB3 equipment on the fourth shelf, Bona PC and two channel stimulus connection box on the fifth shelf below the top shelf and the touch screen on the VESA swivel mounting post on top of the cart.

Connect components as per ORLab™ Quick Installation Guide. Follow all steps 1 to 12, connecting ORLab™ items together with cables provided in the Power and Cabling Kit and Accessories Box and ensuring that cables are tightly secured. Note that mains cords must be passed first through the MP0533 retaining bracket before being secured or connected to power supplies.

In the case of the Atricured-supplied mobile Cart, transformer and most wiring will be pre-installed. Connect the MP3014 Stimulus Connection Box to the Pace Output connector on MP3008 SGU and connect stimulus outputs to stimulus inputs of your 3rd party catheter connection equipment. Connect Ext1_ECG input to a high level ECG output of a third party ECG Monitor via 5 m cable provided, MP3313. Refer to Compatible Equipment for a list of compatible ECG monitors.

Secure mains cords. Ensure that all components mains power cords are connected only to the Micropace supplied isolation transformer, never directly to non-isolated mains power outlets. Ensure mains cords are secured to the isolation transformer with supplied metal bracket and power supply units are restrained and secure so that mains cords can not be removed without a tool. Ensure printer is secured to its shelf and access to the printer mains cord is restricted without use of a tool. The printer power cord must be permanently attached to the printer; do not attempt to disconnect it.

Install Touch Screen. Stand the touch screen on a stable surface or if installing on Atricure-supplied cart, dicard the stand and secure onto VESA mounting. Connect all cables to it as per Quick Installation Guide diagram below. Ensure that touch screen is powered by the supplied MP3300 DC power supply and not mains voltage. Secure the supplied MC0537 Touch Screen DC plug cover bracket over the DC and mains power inlets on the touch screen using supplied screws and washers.

Calibrate Touch Screen. From Current Study page, go to the Calibrate Touch Screen page (then) and using your finger or stylus follow instructions on screen. Ensure that you calibrate from the eye level of the future user to minimize parallex errors.

Calibrate external ECG signal display. The ORLab™ can display a surface ECG signal on its Channel 1 from an external high level signal source inputed into the ECG-1_INPUT on the Stimulus Generator Unit. You must enter the external ECG Monitor's Gain value into the ORLab's Administration Settings Page (accessible via the spanner icon on Current Study Page). Verify this value (or if value is unknown, derive it) using the following steps.

Connect ORLab™ SGU's ECG-1_INPUT to your third party ECG Monitor and set ECG scale to 10mm/mV on both the ECG Monitor and Chanel 1 of the ORLab. Use an ECG simulator to generate an ECG waveform near full scale on the ECG Monitor. Adjust the ECG Monitor's Gain value onn the ORLab Admin Page to make ECG size on ORLab display same as on the ECG Monitor.

Configure ORLab™ Software. Ask user for preferences and observe his/her preferences during intial clinical studies for default values for stimulation parameters and ECG scales for each channel for the two protocols – Sense-Pace and Burst-Stim. Set these preferences in the Interactive Configuration Page for the each of the protocols (then buttons). Refer to relevant sections below for other configuration parameters.

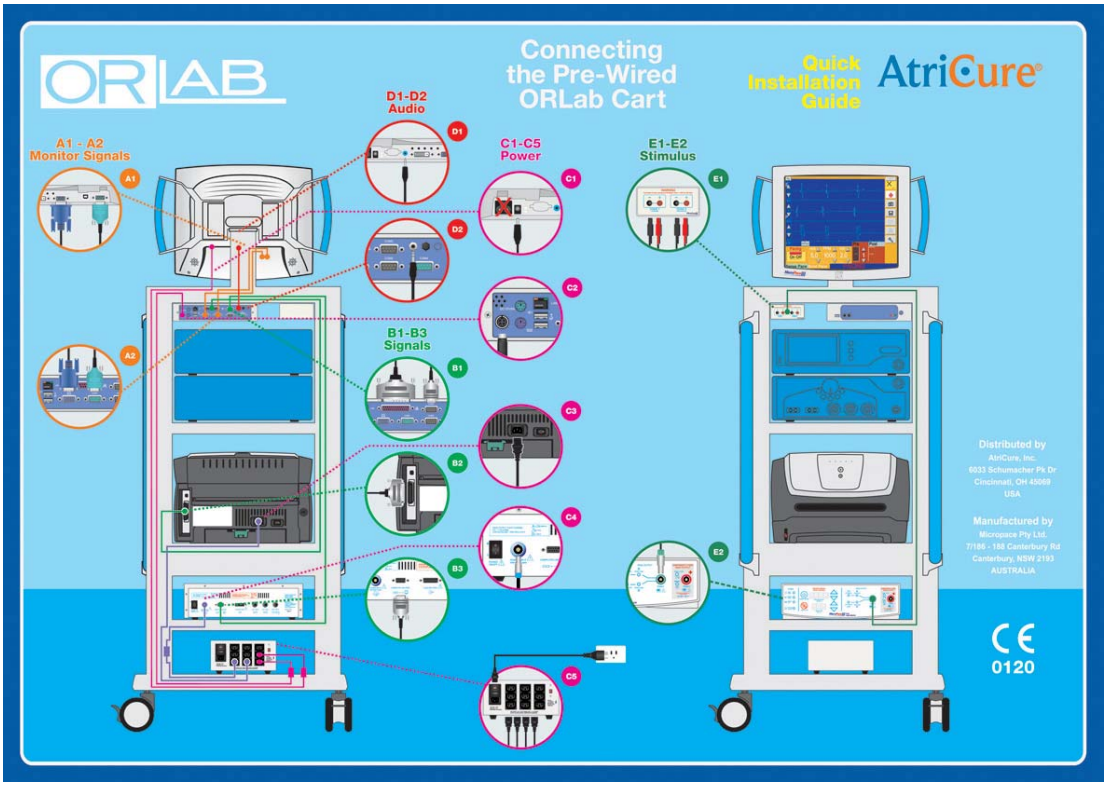


Figure 3 ORLab™ Quick Installation Guide – front and back pages.

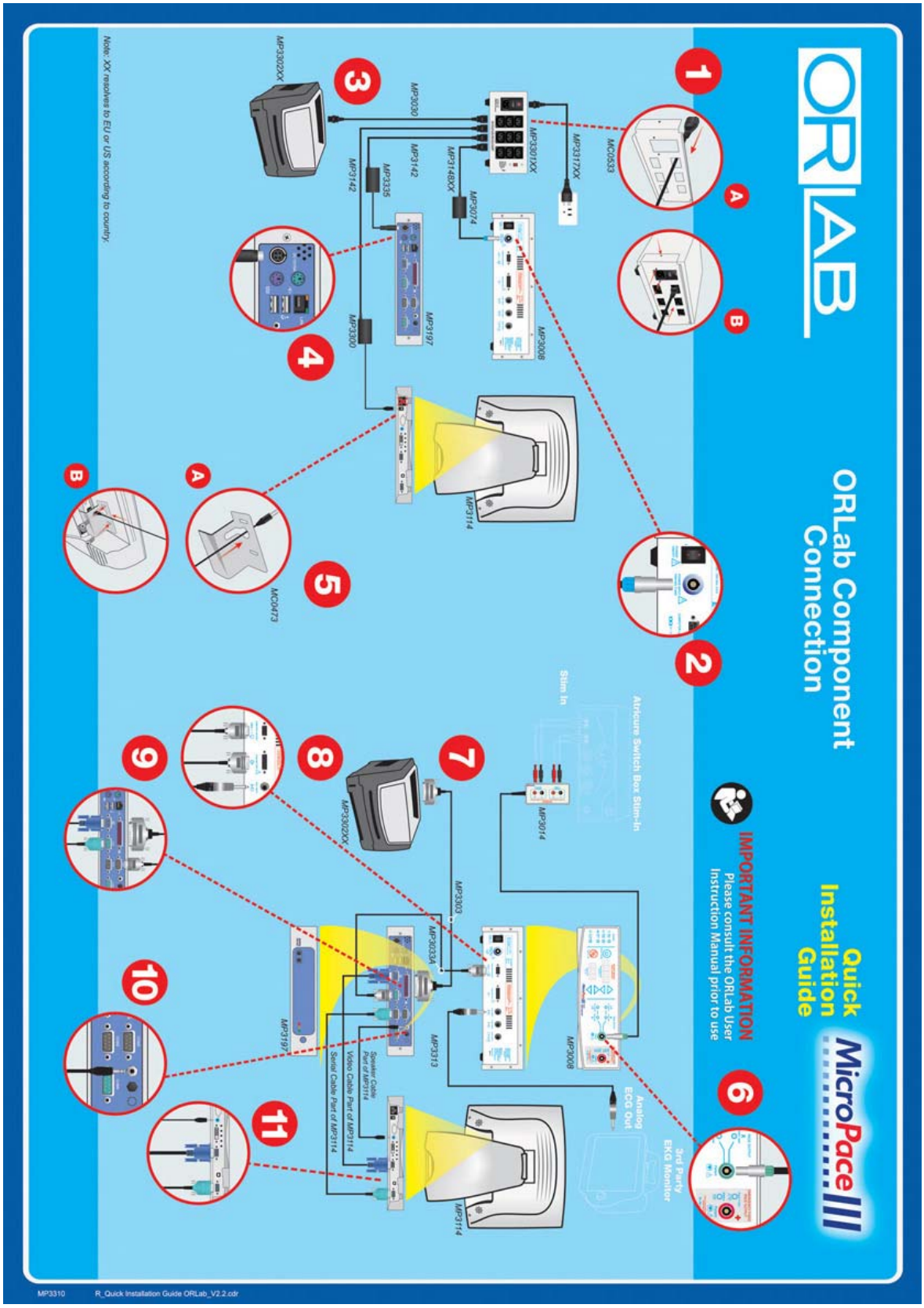


Figure 4 ORLab™ Quick Installation Guide – inside double page showing connections.

6. VERIFYING THE SYSTEM

The ORLab™ system must be verified to operate correctly prior to use. The Customer must also be instructed in its use prior to operating the system. Follow instructions below and complete the subsequent checklist before completing commissioning of the system.

1. ***Verify Isolated Mains.*** Visually verify that all Micropace ORLab™ Stimulator components – PC, SGU, Laser Printer and LCD Touch Screen, are connected to the Micropace supplied Medical Grade Mains Isolation Transformer e.g. MP3301EU/US.
2. ***SGU POST passes.*** Verify that Stimulus Generator Unit (SGU) powers on without errors (front panel displays "PC").
3. ***PC Software Application clean launch.*** Verify that application launches without errors and displays Current Study page.
4. ***Test Pacing channels***. Insert Stimulus Test LED, MP3058 (from the Installation Kit in the Accessories Box) into the Stimulus Connection Box (MP3014) Channel 1, red connector to red, black to black and commence pacing into Channel 1 at 25mA, 2ms. Verify that LED lights Yellow with pacing (If light is red, fault exists causing output polarity reversal). Repeat for channel 2. Connect the stimulus output to the AtriCure® Source Switch Accessory with appropriate AtriCure® cable.
5. ***Verify Emergency Pacing.*** Connect Test LED to Chan2 output of MP3014 Stimulus Connection Box; change the Stimulus Output connector from the SGU Pace Output (green socket) to the Emergency Fixed Rate Pacing Output (red socket). Observe pacing. Restore stimulus cable to green 'Pace Output' socket.
6. ***Verify External ECG sensing.*** Connect ECG simulator to ECG Monitor surface leads and verify that the ORLab™ Stimulator displays the ECG on the screen (if you don't have a simulator, create some noise on channel by touching the electrodes).
7. ***Verify Touch Screen.*** Verify LCD screen touch function by starting and stopping Emergency pacing and exiting and re-entering Application. Recalibrate touch screen if touch response does not line up with touch buttons.
8. ***Test Print Page.*** Select from Sense Pace protocol the Review page button and press Print Single Page. Verify that the printer has printed a single printout of the review page displayed on the screen.
9. ***Biomedical Engineering Safety Acceptance.*** Organize for Biomedical engineer to perform acceptance test of the entire installed system according to the health facilities' procedure's (generally UL/IEC60601-1 safety test.

If problems are encountered, refer to the troubleshooting guide in this User Instruction Manual. Make a record of the verified installation and sign and date according to your company's quality system and file as required.

6.1 Train Customer

1. ***Customize Stimulator settings.*** Sit down with the responsible customer – chief technician or physician and set up various defaults for the Stimulator – such as default Pace Rate values in protocols. Save defaults.
2. ***Demonstrate User Instruction Manual***. Inform the electrophysiologist and technician of the safety features of the stimulator and direct them to the relevant sections in the User Instruction Manual where safety warnings are listed.
3. ***Demonstrate Help feature***, (icon '?') available throughout the software application. Explain Safety Diagram as an aid to safety items below (Help topic: "Safety and Setup").

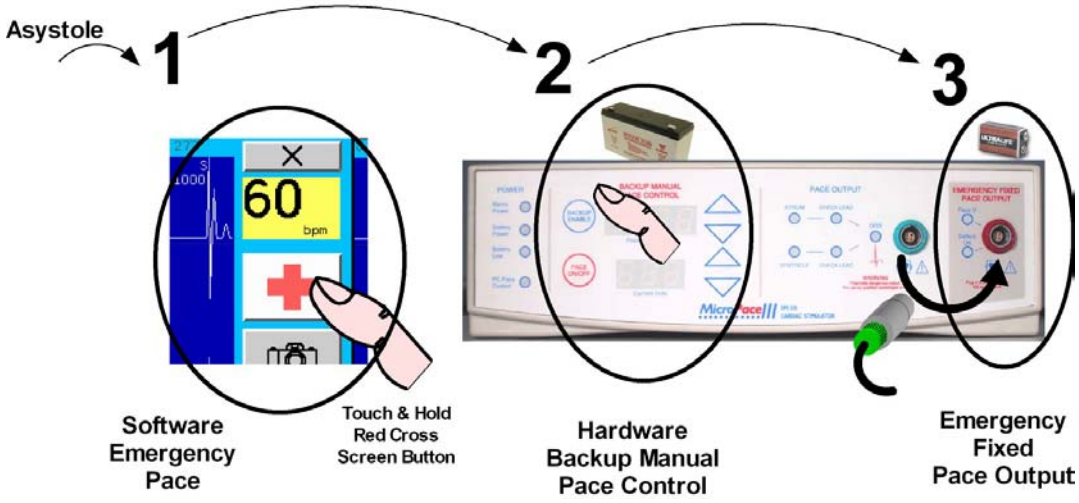


Figure 5 ORLab™ three systems for backup pacing

4. ***Demonstrate Emergency Pacing key.*** While Stimulator is in normal PC control mode and in any protocol, press Red Cross symbol to demonstrate Emergency Pace protocol whereby both channels are immediately paced.
5. ***Manual Backup Pacing Mode*** - Demonstrate this safety mode (in cases of PC failure) by pressing the 'BACKUP ENABLE' button on the Stimulator (or disconnecting Serial Cable MP3033A). When red numerals ("600" and 5.0") appear on display, press 'PACE ON/OFF' button to pace. Adjust 'Interval' with up/down arrow buttons. Pacing is always into both channels. Hit the Connect SGU button on the LCD screen and [YES] to re-enter PC Control mode.
6. ***Demonstrate Fixed Rate Emergency Pacing Mode***. Instruct the user that should the SGU fail itself, they can use this feature. Connect Stimulus Test LED, MP3058 to Stimulator Output on the Ventricle / Chan 2 output and on the SGU front panel, remove the Stimulus Connection Box's green connector from the green Pace Output socket and insert it into the red Emergency Fixed Pace Output socket. The self-contained emergency circuit will commence pacing at 100 pulses per minute, 5mA and 2ms width (it detects presence of load resistance on the output and commences pacing automatically).

6.2 Micropace ORLab™ Installation Checksheet

The following checklist is to be performed after installation of the Micropace ORLab™ Stimulator and before first 'live' EP case. All items must pass for installation to be accepted. Any exceptions / failures must be signed off by Clinical specialist or engineer prior to use on patients.

Item	Test Method	Expected	Observed	P/F
1.Mains Isolation	Visually verify that all Micropace ORLab™ Stimulator components – PC, SGU, Laser Printer, and LCD Touch Screen, are connected to the supplied Medical Grade Mains Isolation Transformer, and secured so cord cannot be disconnected from isolation transformer without use of a tool.	All components plugged into Isolation Transformer and cords secured.		
2.SGU POST	Energize the SGU and observe all LED's during Power On Self Test (POST)	All LED's light momentarily (except Emergency Fixed Rate Pace) and no errors appear on SGU display.		
3.Software Application Launches OK	Observe launch of ORLab™ Stimulator Software Application without error messages.	ORLab Current Study screen appears, no error messages		
4.Stimulation path & Polarity OK.	Configure Stimulator to stimulate Chan1 at 25mA 2ms at 100ppm. Insert Test LED (MP3058) into Stimulus Connection Box, MP3014, Chan1, red connector to red, black to black. Start pacing and verify yellow LED lights with each pulse. If red LED lights then polarity is reversed.	Yellow LED flashes with each stimulus.		
5.Emergency Fixed Rate Pacing OK	Connect Test LED to Chan2 output of Stimulus Connection Box; change the connector from the SGU Pace Output (green socket) to the Emergency Fixed Rate Pacing Output (red socket). Observe pacing. Restore stimulus cable to green 'Pace Output' socket.	Pacing sound is emitted and yellow Test LED lights at 100 ± 20% ppm. 'Battery OK' indicator lights after 1-4s.		
6.External ECG Visible	Connect ORLab™ SGU's ECG-1 INPUT to your third party ECG Monitor. Use an	ECG is seen on Stimulator screen (top channel)		

Item	Test Method	Expected	Observed	P/F
	ECG simulator to verify that ORLab displays ECG on its screen.			
7. Touch screens active	Verify LCD screen touch function by starting and stopping Emergency pacing and exiting and re-entering Application.	Pacing starts on sustained press of Emergency button and stops with press of Pace On/Off.		
8. Printer functional.	Print Test one page from Review screen.	Printer prints Review Screen Page as displayed on the screen.		
9. Biomed Engineering approval	Health facility's Biomedical Engineering Dept. is generally required to test and accept the installed system for electrical safety; ensure that this has been done.	Biomedical Engineering acceptance verified.		
10. Customer trained	Responsible customer representative has been trained as per above training.	Customer able to perform items in Section 6.1 above.		

Health Facility Name:	
Health Facility Location:	
ORLab Stimulus Generator Unit Serial No.:	
Installation officer name:	
Installation officer signature:	
Date:	

Table 5 Micropace Installation Checksheet

7. USING THE ORLAB™ CARDIAC STIMULATOR

7.1 Switching on and off the system

Switch on the computer and the EPS320 Stimulus Generator Unit (the power switches are located on the LCD Display on its right edge, on the PC on the front panel and on the SGU on the rear panel).

The stimulator Current Study screen will appear automatically after boot-up. The computer software will then establish a serial RS232 link with the Stimulus Generator Unit. This may take a minute. If the software prompts you whether it should re-connect to the Stimulus Generator Unit (SGU), press 'yes'. Recheck that the Stimulus Generator Unit is switched on by the presence of a green (not yellow) light above the MAINS POWER label on its front panel.

Switch off the system. The ORLab™ system may be safely switched off and on at the mains power switch. Upon switching system off and on or after power interruption, application displays the Current Study page and user may continue the current study ( ) preserving saved data or commence a new study ( ).

7.2 Using the computer

The ORLab™ Cardiac Stimulator system comes with a Bona Light System PC; refer to "Connect System Components" section on how to connect the PC to other system components. The front panel of the computer shown in **Error! Reference source not found.** allows the user to connect an USB or sound output device as well as providing the user with PC activity indicators.

1 USB Port
2 Microphone In
3 Line Out
4 LAN LED
5 HDD LED
6 Power LED
7 Power Switch

Figure 6 Computer front panel

FEATURE	Explanation
1. USB Port:	Connection for USB device, such as USB Flash Drive. Used only for upgrade of software or transfer of data files. PC must be re-booted to recognize USB Flash Drive, contact Micropace for compatible flash drives.
2. Microphone In:	Feature is not used – do not connect to this port.
3. Line Out:	Connection for MP3113 touch screen audio Input.
4. LAN LED:	Network activity indicator, not used.
5. HDD LED:	Indicates disk activity
6. Power LED:	Indicates computer is switched on
7. Power Switch:	Push to toggle Computer On/Off (NB: If power is removed from the PC, the PC restarts automatically on reconnection of power, however, if you switch off PC by pushing this button, then PC will remain off until button is pushed again.

Table 6 Computer Front Panel Explanations

7.3 Using the Touch Display

The ORLab™ Touch Screen is a 15” touch LCD display with a touch-sensitive surface using resistive technology:

- You may use your finger, gloved finger or a stylus to activate touch screen buttons.
- Menus and submenus are navigated by touching their names (e.g. Burst Stim in Figure 7)
- Numerical parameters may be adjusted by touching adjustment Up/Down buttons (Figure 7) or by tapping the number, which will display a numeric or alpha-numeric keypad for entry (Figure 9).
- Press the Red Cross Emergency Pace button at any time to start pacing immediately (Figure 8).
- Press Exit cross icon to exit menus and ORLab™ application.

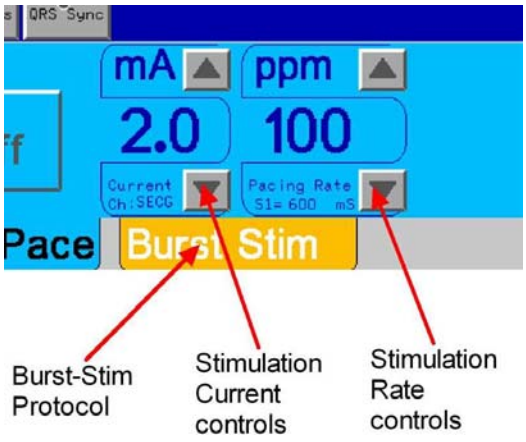


Figure 7 Stimulus Parameter adjustment

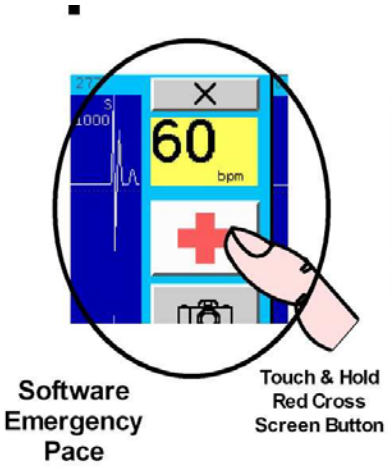


Figure 8 Emergency Pace

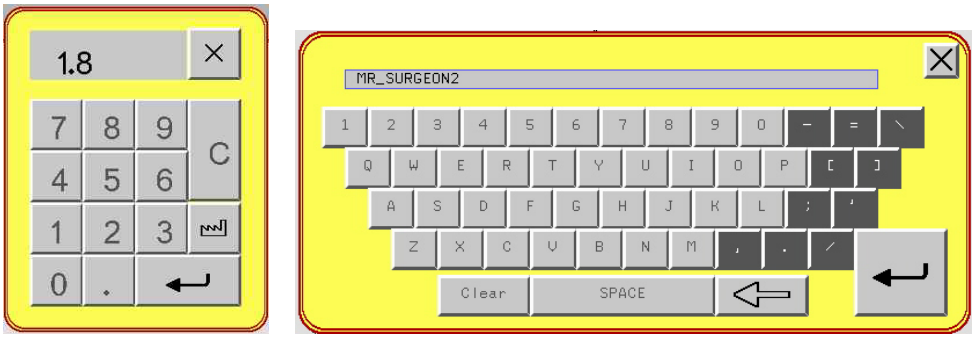
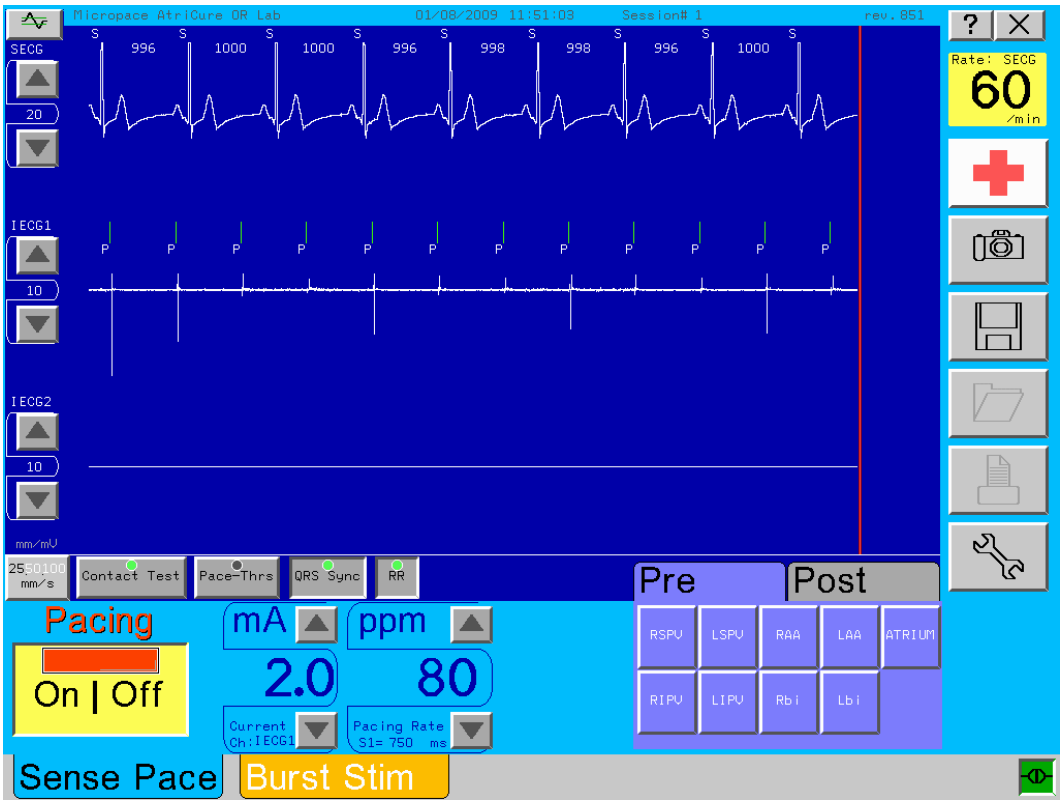


Figure 9 On-screen Numeric Keypad and Keyboard for Data Entry



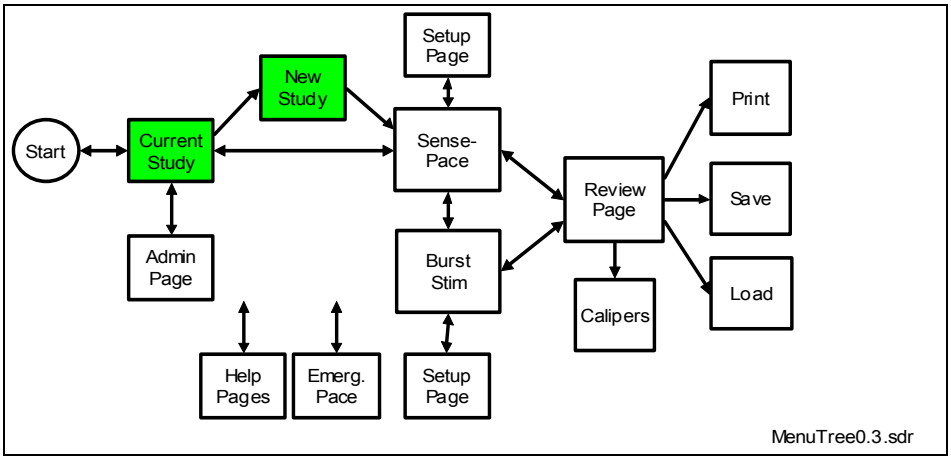
Touch Button	Function
PACE On/Off STIM On/Off	Brief touch toggles Pacing On/Off. Sustained touch – Pacing while pushed In Burst Stim mode, sustained push required initially to activate button.
Current, mA	Adjusts stimulation current amplitude, may be incremented / decremented with associated arrows or new number entered by tapping number and entering into a numerical keypad.
Pacing Rate, ppm	Adjusts stimulation rate, may be incremented / decremented with associated arrow or number entered with a keypad.
SENSE PACE	Selects Sense Pace protocol. Needs sustained touch to activate.
BURST STIM	Selects Sense Pace protocol. Needs sustained touch to activate.
Ablation State	Select Pre or Post RF Ablation label to be associated with recorded ECG trace.
Site	Select recording / ablation site code by Left / Right and a number to be associated with recorded ECG trace.
ECG Gain	Adjusts ECG display size for associated channel.
25 50 100, mm/s	Toggles screen display sweep speed
QRS Sync	Toggles On/Off sync of 1st stimulus to P or QRS in ECG
Emergency Red Cross	Starts emergency pacing into both channels. Needs sustained touch to activate.
	Toggles left controls from ECG Gain to Peak Detect Threshold controls.
?	Help function
X	Exits menu / application

Table 7 Summary of main touch buttons and their functions

8. USING THE ORLAB™ SOFTWARE

8.1 Screen Page Layout

ORLab™ screen pages are laid out in the following tree structure.



8.2 Starting a new study

The ORLab™ software launches automatically on powering the ORLab™ and launches into the Current Study Page.

To start a new study, press New Page (Blank Page icon). Touch the Surgeon's Name to change the field. Note that Date and Time Started fields are automatically locked-in at start of study and cannot be changed.

To continue current study or the last study when system was turned off, press Continue (Right Arrow icon).

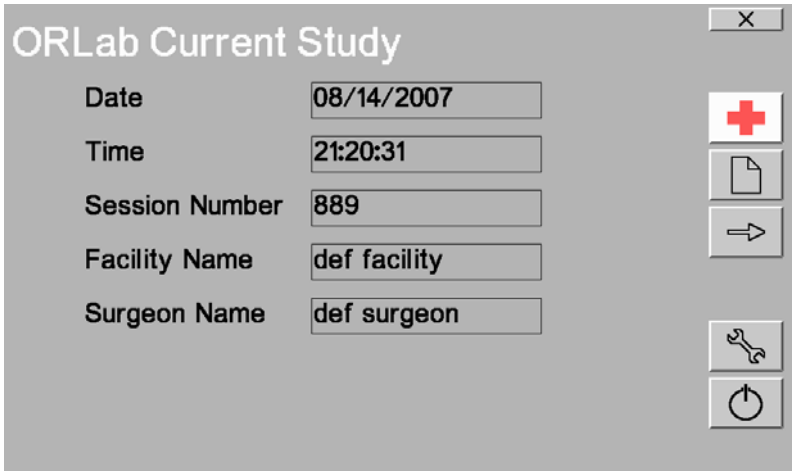
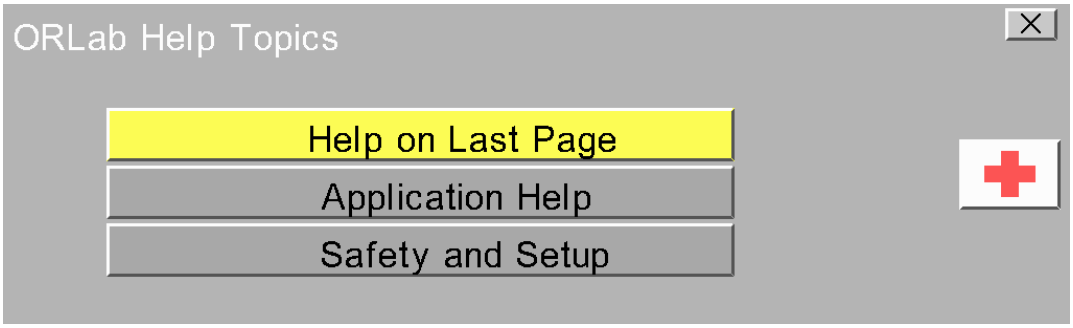


Figure 10 Current Study Entry Page

Note: To adjust Current Time or Date or to edit Facility or Surgeon's Name drop-down list, go to Service Page (Spanner icon). To exit program into its standby mode, press Stand-by (Circle with line icon) or Quit (Cross icon).

8.3 ORLab™ Help Facility

Context-sensitive on line help is available on most ORLab™ pages by touching the question mark in right upper corner. You will be presented with following menu:



Touching first option "Help on Last page" displays help for current ORLab™. Options below that display multi-page help for the listed topic in a format shown below:

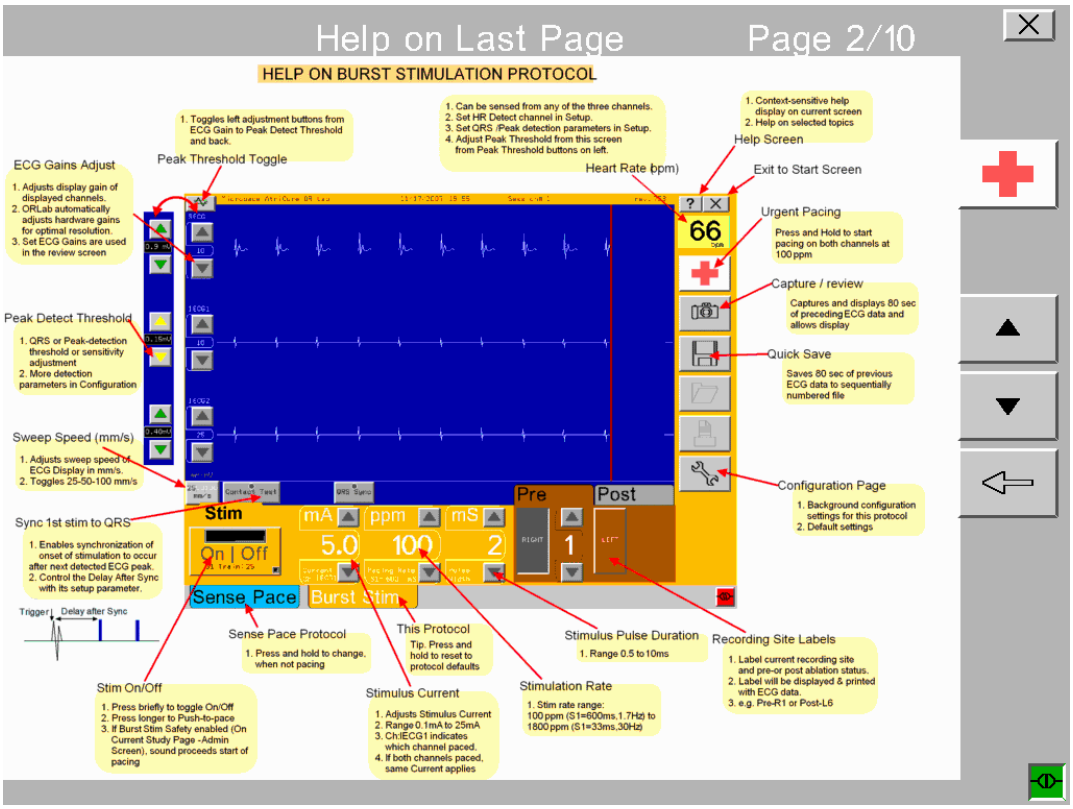
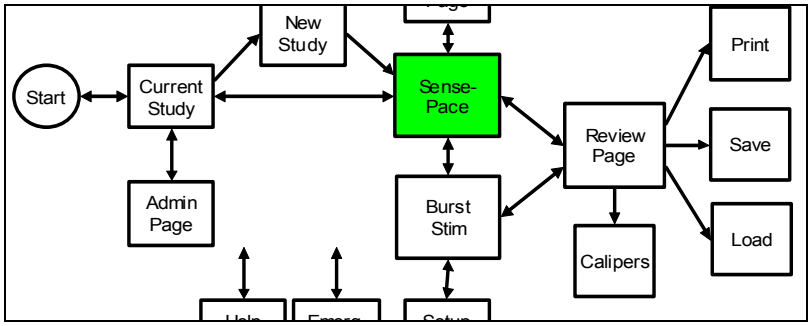


Figure 11 Example of an ORLab help page.

8.4 Main Study Page - Sense Pace Protocol

This protocol may be used for passive sensing and recording of cardiac rhythm or for induction and termination of tachycardia and determination of cardiac conduction block.



Continuing from the Current or New Study Page enters the ORLab™ Main Study Page. This page displays three real-time ECG traces with amplitude controls and a number stimulation parameters.

8.4.1 Controls include:

- Surface ECG Amplitude Control Button: (5, 10, 20 mm/mV)
- Intracardiac ECG Amplitude Control Button: (1, 2, 5, 10, 25 mm/mV)
- Sweep Speed: (25 and 50 mm/s, and 100mm/s)
- QRS Detection threshold (0.01 to 18mV)
- Stimulus Current: (0.1 to 25mA)
- Pacing Rate: (30 to 350ppm)
- Ablation State labels: “Pre” and “Post”
- Site Annotation labels: (9 labels)
- Contact Test
- Pace Threshold
- QRS Sync
- RR Interval Display

To adjust these parameters, touch the associated Up/Down buttons or with Current and Pacing Rate, you can enter a new value by tapping the numeral to display an on-screen numeric keypad.

Rate/min display on a yellow background indicates 3-beat average Rate/min of detected sECG /iECG complexes. Note this can represent heart rate or atrial rate, depending on sense location.

Emergency Pace button located on the top right hand side, if pressed for 1 second will start pacing at a pre-determined safe rate.

Review Snapshot captures last 80 seconds of ECG and stimulation event data and allows user to scroll through data, measure timing and Save or Print to laser printer.

Save button saves last 80 seconds of ECG and stimulation event data to file without reviewing the data for subsequent analysis.

Setup button allows advanced setup and defaults for pacing parameters.

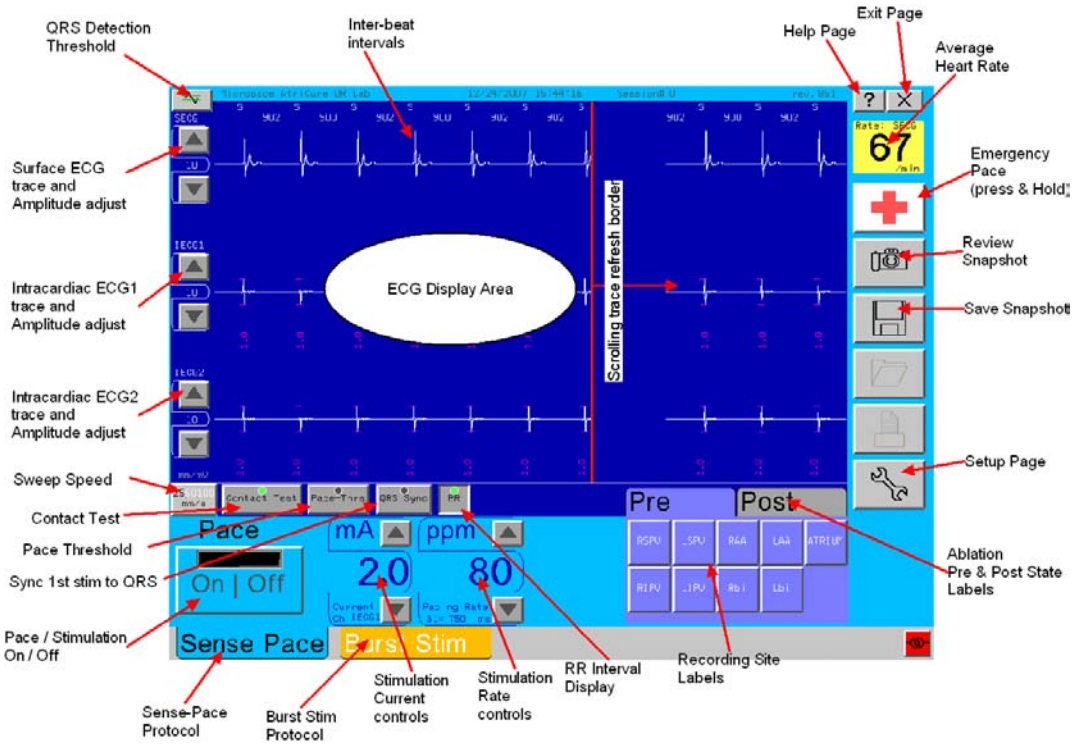
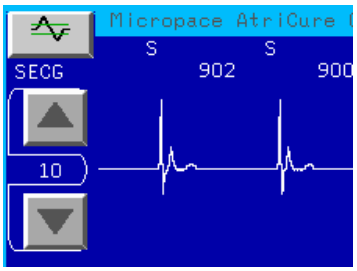


Figure 12 Sense-Page protocol explained

The ECG Display also indicates Detected ECG peaks with a small ‘S’ and Pacing events with vertical lines and a small ‘P’. RR intervals are indicated in milliseconds as shown on the right.



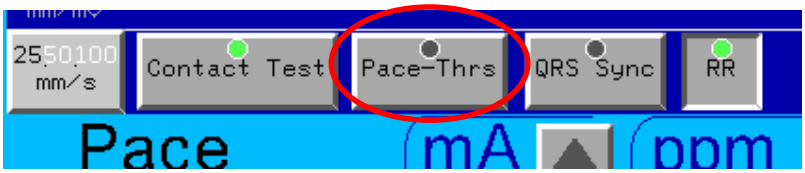
8.4.2 Conduction Block Determination

Determination of cardiac conduction block may be performed by pacing one side of candidate conduction block and sensing from the other side.

Follow the following steps to study conduction block:

1. Adjust ECG amplitudes to occupy 2/3 of vertical space for each.
2. Select Pre- or Post Ablation tabs and select Cardiac Site being tested; these labels will be stored and printed with any data.
3. Adjust Stimulation Current with up/down buttons or double tapping Current to enter value via keypad.
4. Adjust Pacing Rate similarly.
5. Start pacing by pressing Pace On/Off
6. Observe for absence of synchrony between paced and sense channels or difference in heart rates between surface and intra-cardiac sense sites.
7. Note: Stimulus Pulse Duration is adjustable from Setup Page.

8.4.3 Pacing threshold measurement



Press Pace-Threshold button to perform pacing threshold, the Stimulator sets to a predefined start value and automatically decrements Current in steps. When you have detected loss of capture, stop pacing and set pacing to twice the threshold (but always >1 mA). Threshold button pops out when stop pacing, adjust Pacing Rate manually.

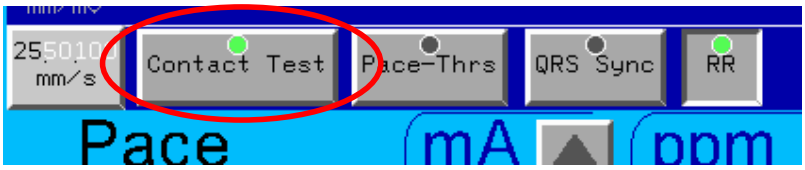
8.4.4 Synchronizing start of pacing to PQRS

To synchronize First S1 to QRS, press **QRS Sync** button. When you then start pacing, stimulator will wait until after first QRS is detected, then wait a pause period before pacing starts.

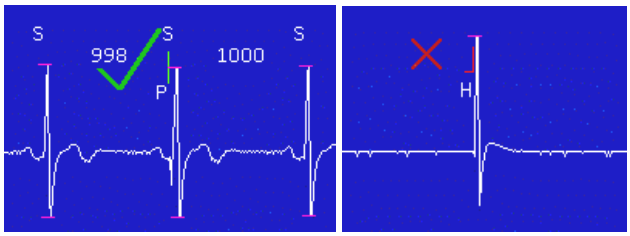
The button lamp signals the sync state with colors:

1. Black: Sync is off (button is released)
2. Green: Sync Enabled but on standby (not pacing or pacing 1st Stim delivered)
3. Orange: Pacing started and waiting for QRS Sync
4. Red: Pacing On and Timeout reached while waiting for Sync.

8.4.5 Contact Test



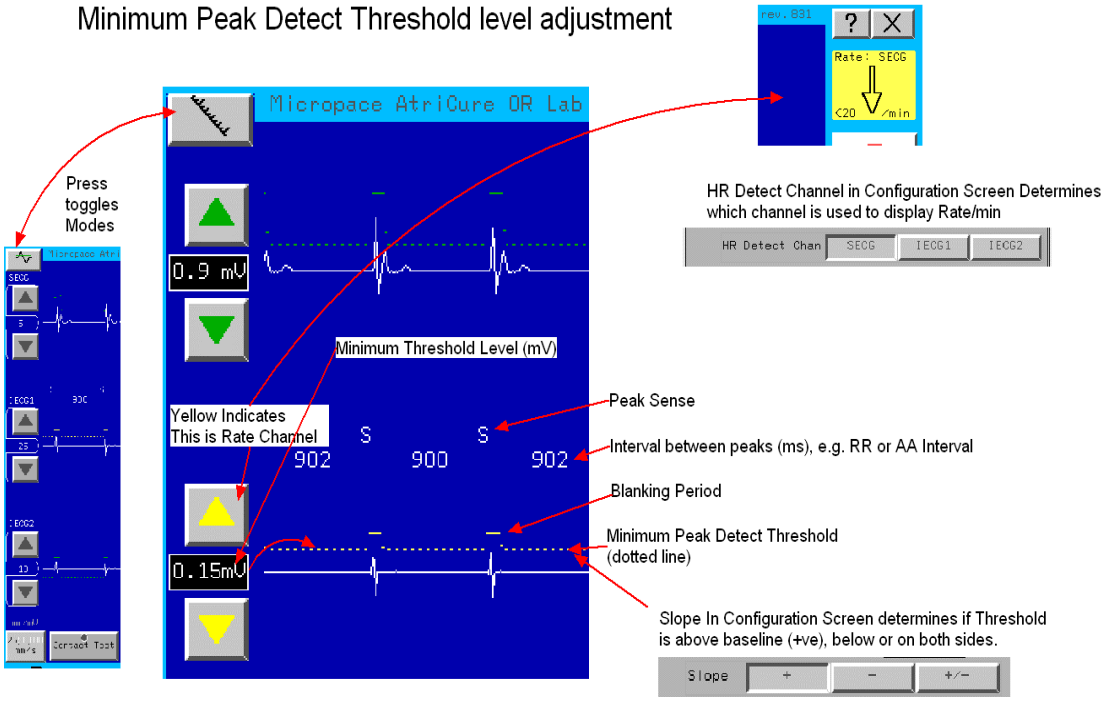
When sensing for electrograms, poor or absent contact of electrode onto the myocardium may falsely simulate absence of electrogram. Use Contact test to verify that adequate contact with myocardium exists. This test issues a sub-threshold (0.1mA 1ms) stimulus into the sensing electrode and resulting impedance is measured. Poor contact with impedances greater than 3000 ohms is indicated by a red cross marked on the ECG trace; good contact < 3000 ohms displays a green tick on the ECG trace.



In the case of hand-held electrodes, once good contact is documented, good contact persists only as long as the electrode position is maintained by the operator, which may be expected for no more than, say, 5 to 30 seconds.

8.4.6 Peak Detection / QRS detection

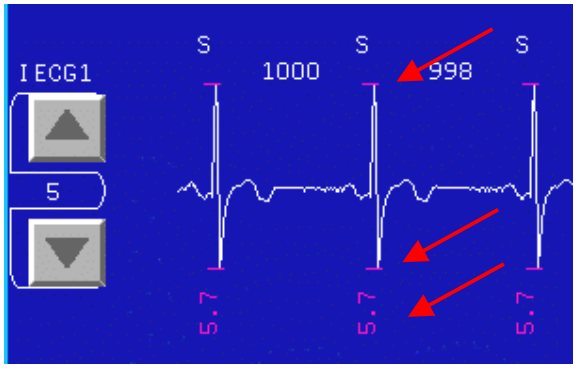
Peaks in SECG and IECG may be detected, interval measured and displayed and also Rate/min measured and displayed.



8.4.7 Peak to peak interval / RR Display

This may be toggled on / off with RR button on main page, preferred default state may also be saved in the Configuration page with “RR on ECG Display Enable”.

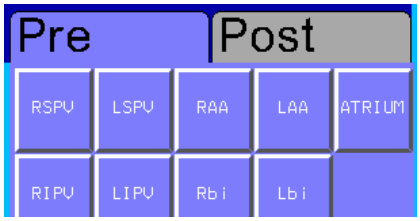
8.4.8 Amplitude Measurement & Display



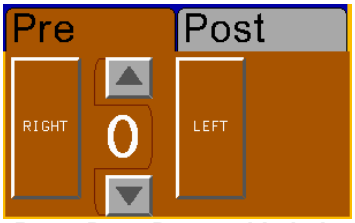
If enabled with Sense Pace Configuration Parameter “Amplitude on ECG Display Enable”, Application marks the detected peak and trough of IECG complexes and measures and displays the amplitude values, in mV displayed in red color under the ECG complex.

Peaks must be correctly detected for correct amplitude to be measured – use above Minimum Threshold adjustment and Configuration Page Peak Detection parameters to ensure optimal peak detection.

8.4.9 Ablation State labels: “Pre” and “Post”



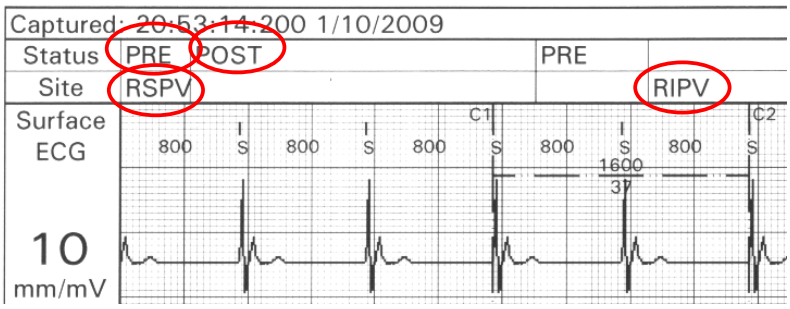
Sense-Pace Protocol labels



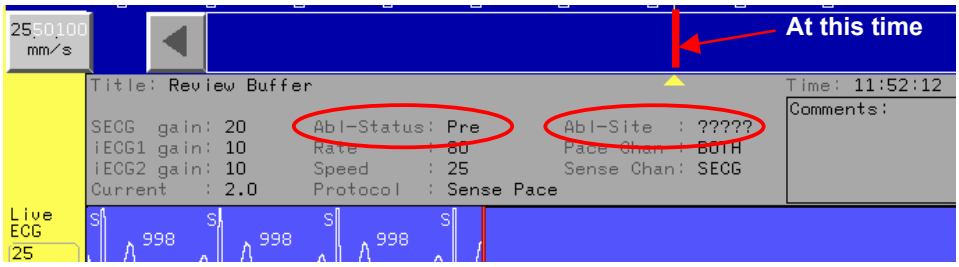
Burst Pace Protocol Labels

Press Pre or Post tabs to indicate on recorded or printed ECG traces whether recorded prior to or post RF ablation. Select Anatomical Site annotation label corresponding to the site of ECG recording to indicate this also on the ECG records.

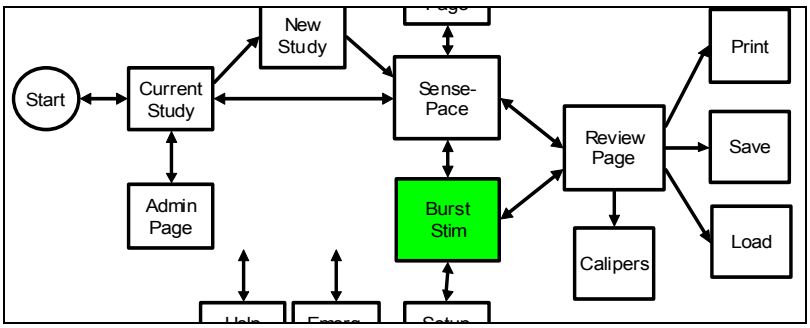
Annotation is displayed on printout as illustrated below:



On the Review Screen, Ablation Status and Site Label valid at the centre of the display, indicated by yellow triangle, are displayed in the data under the trace:



8.5 Burst Stimulation protocol



High Frequency Burst Stimulation may be used to stimulate Vagal ganglia or ganglionated plexi from the epicardium or endocardium. Select this Protocol by pressing **Burst Stim** tab for 1 second.

This protocol has same ECG Amplitude and Sweep Speed display and controls as Sense Pace protocol.

8.5.1 Controls include:

- Surface ECG Amplitude Control Button: (5, 10, 20 mm/mV)
- Intracardiac ECG Amplitude Control Button: (1, 2, 5, 10, 25 mm/mV)
- Sweep Speed: (25 and 50 mm/s, and 100mm/s)
- Stimulus Current: (0.1 to 25mA)
- Stimulation Rate: (100 to 1800ppm)
- Ablation State labels: “Pre” and “Post”
- Site Annotation labels: (Numerals 1 to 16)
- Contact Test
- QRS Sync
- RR Interval Display

WARNING:

Burst Stimulation is likely to cause fibrillation in stimulated chamber. You must (i) ensure that stimulation electrode is located on the atrium and not ventricle – observe anatomical location and timing of intracardiac electrogram which should be coincident with P wave on surface ECG and (ii) ensure you are equipped to defibrillate the heart in case of ventricular fibrillation.

Follow these steps to stimulate Vagal structures:

1. Select Pre Ablation status tab
2. Select anatomical area being stimulated – Left or Right and Number 1-16 (refer relevant texts)
3. Select required Stimulation Rate, Current and pulse Duration
4. Press Pacing On for 5-10 seconds
5. Observe ECG display for effects.
6. If attempting to elicit bradycardic reflex, cease stimulation when either slowing of heart rate by 50% or asystole is detected.
7. Use Emergency pacing if patient requires pacing support for a few seconds.

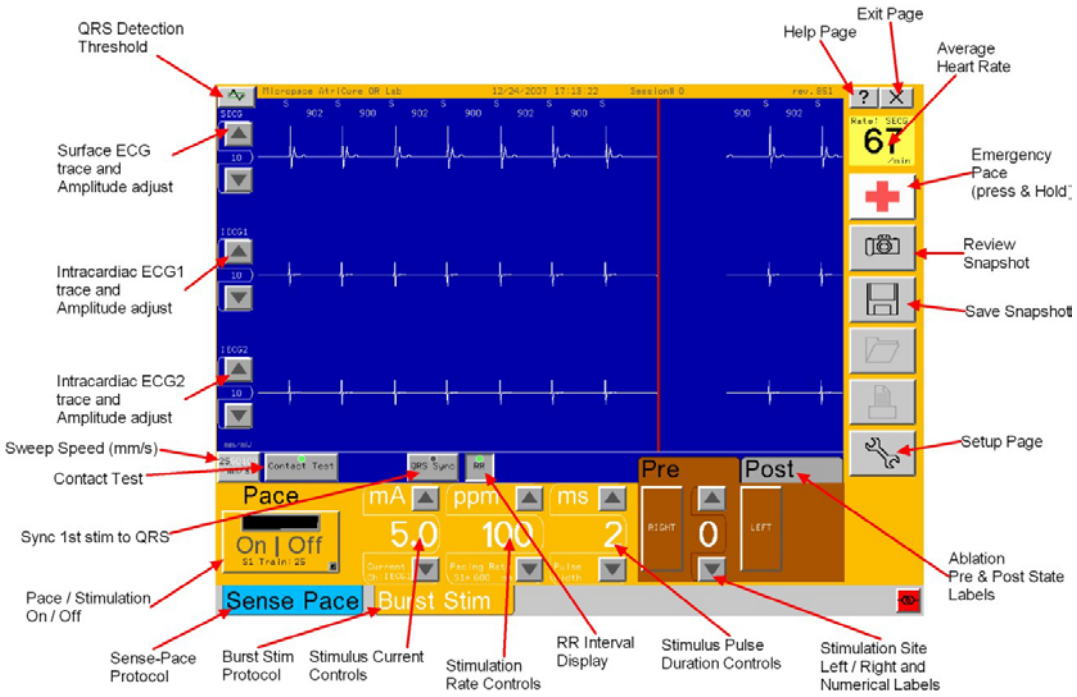


Figure 13 Burst Stim Protocol with Stim Duration and specific ablation labels

8.5.2 Burst Stim Button Safety Delay Tone

Accidental application of Burst Stimulation to unintended sites in the heart, such as the ventricle, may cause a hazard. The Burst Protocol in the ORLab™ has a delay and a warning tone on the Pace button to warn user that burst stimulation will take place. The level of intrusion of warning may be adjusted in the Administration Page (refer section Administration Page below).

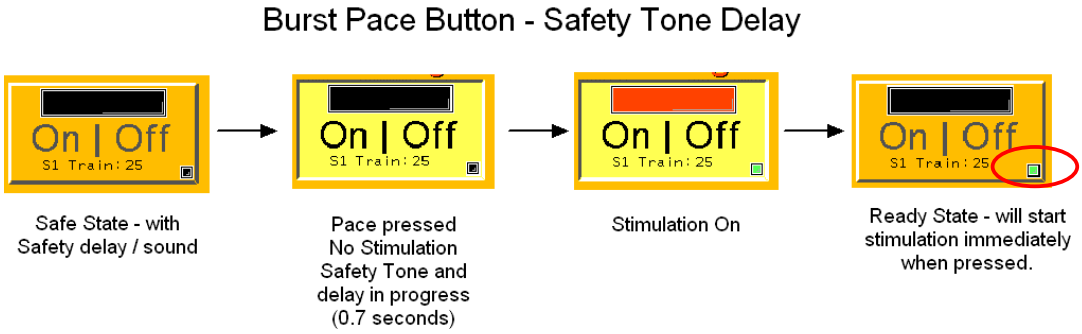
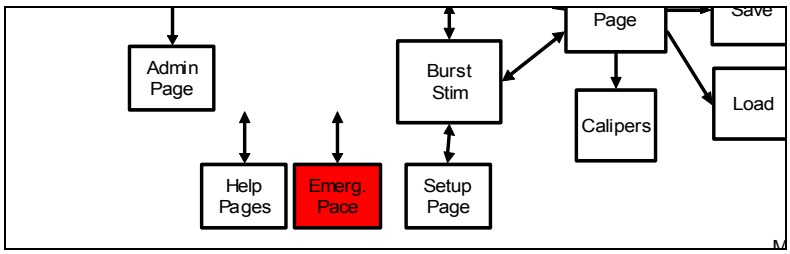

Burst Pace Button - Safety Tone Delay
On | Off
S1 Train: 25
Safe State - with Safety delay / sound
Pace pressed No Stimulation Safety Tone and delay in progress (0.7 seconds)
Stimulation On
Ready State - will start stimulation immediately when pressed.

Figure 14 Burst Pace Safety Delay

8.6 Emergency Pace



WARNING: The ORLab™ is not a life support medical device. The ORLab™ may only be used by qualified physicians or surgeons in laboratories and operating theatres equipped with temporary pacing equipment and defibrillation equipment. Patients who become pacemaker dependent during ORLab™ studies must be paced with approved temporary pacing systems as soon as possible.

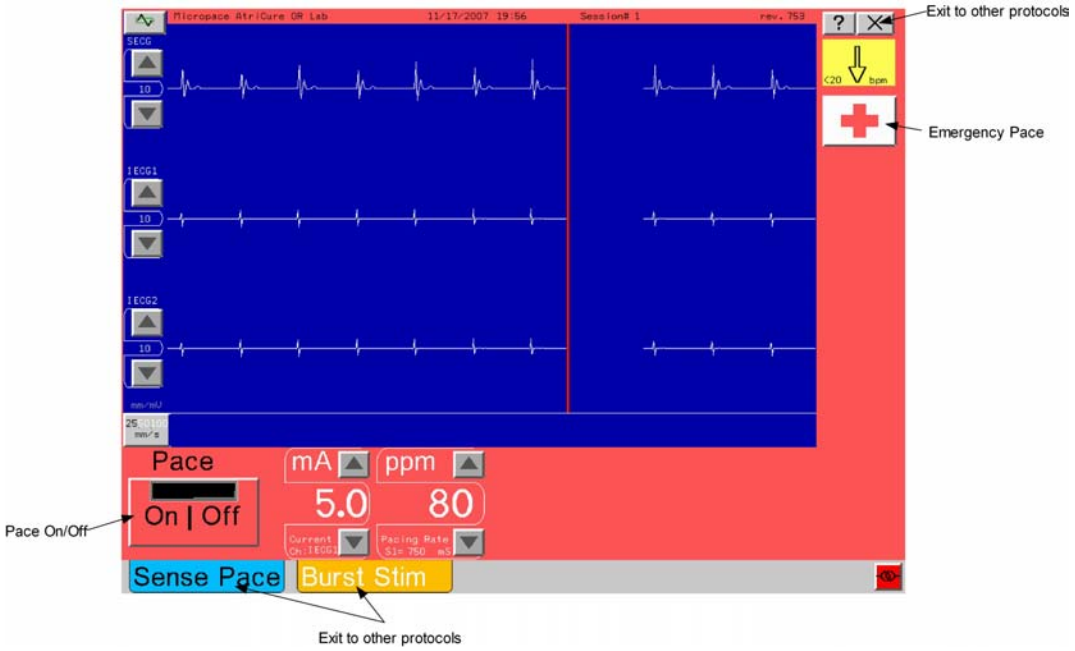


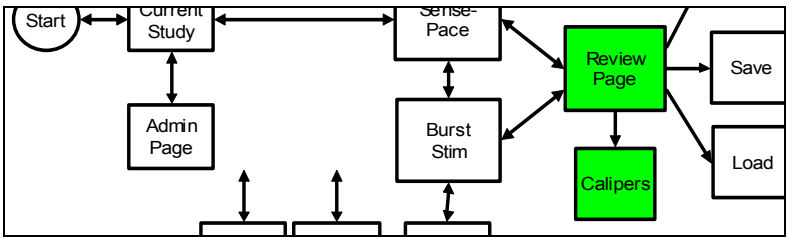
Figure 15 Emergency Pace Protocol

For urgent pacing of patient, press Emergency Pace button for 1 second. ORLab™ will enter Emergency Pace protocol and immediately pace both output channels at a rate of 80ppm with a stimulus current of 5mA and pulse duration of 2ms. The Rate and Current may be changed while in this protocol, but the default settings on entry remain fixed.

Emergency Pace button is located on almost all pages of the ORLab™.

To return to Main Study Page, stop pacing and press Sense Pace or Burst Stim.

8.7 Reviewing ECG's



The ORLab™ continuously stores the last 80 seconds of ECG and Stimulus event data. You may snapshot and review this data from the Main Study Pages (Sense Pace and Burst Stim) at any time other then when you are stimulating by pressing the Review Snapshot button.

The Review Screen displays the three captured ECG traces annotated with graphical Sense and Pace events.

Adjust ECG Amplitude and Sweep Speed as required – a faster 100mm/s sweep speed is available on this page to facilitate ECG inspection. At 25mm/s speed, 80 seconds of data spans 8 pages; position in the file is indicated on the Screen Position Bar. Move traces to left or right by dragging the trace or by using the scroll bar arrows.

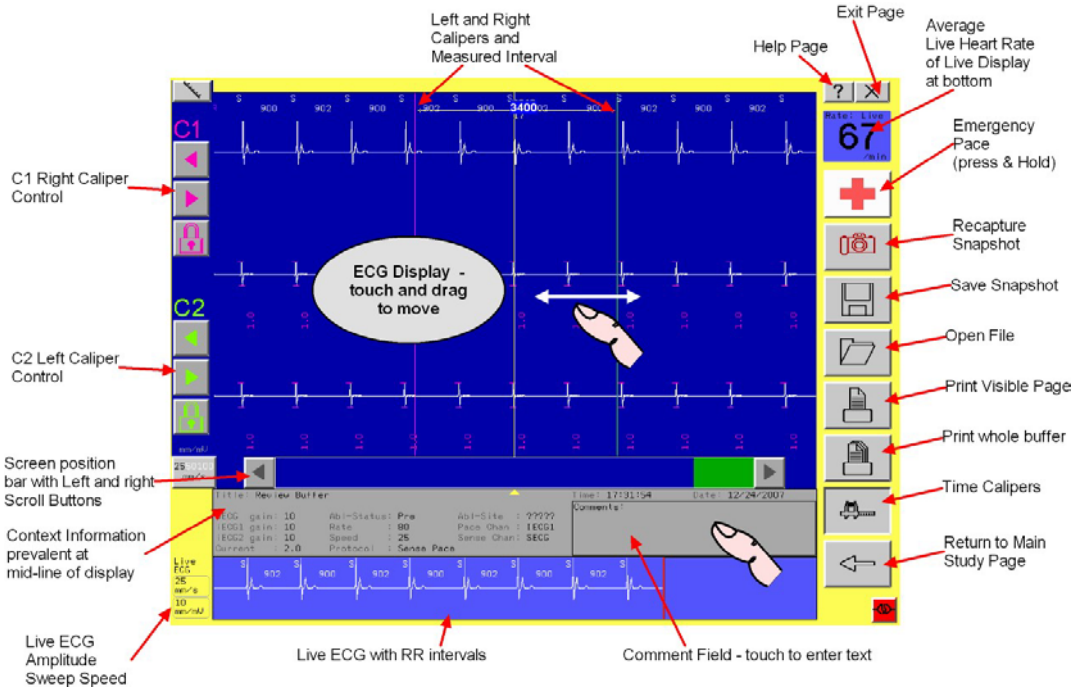

Left and Right Calipers and Measured Interval
Exit Page
Help Page
Average Live Heart Rate of Live Display at bottom
Emergency Pace (press & Hold)
C1 Right Caliper Control
C1
C2
ECG Display - touch and drag to move
Recapture Snapshot
Save Snapshot
Open File
C2 Left Caliper Control
Print Visible Page
Print whole buffer
Screen position bar with Left and right Scroll Buttons
Time Calipers
Context Information prevalent at mid-line of display
Return to Main Study Page
Live ECG Amplitude Sweep Speed
Live ECG with RR intervals
Comment Field - touch to enter text

Figure 16 Review Screen with explanations

Context Information prevalent at the time of the trace displayed at the midpoint of the screen is shown below the traces. Comments may be added by touching the **Comments box.**

Auxiliary **Live ECG** trace is shown at the bottom of the screen and the Rate display continues to indicate the patient's real-time Rate /min.

ECG trace features may be measured with **Calipers**, the visible one page may be printed to laser printer with **Print Page** or the whole 80 second buffer may be printed with the **Print Whole Buffer** button (user is asked to confirm).

If an interesting event is observed on the Live ECG display, the event may be captured by the Recapture Snapshot button. ECG Traces at the beginning of the 80 second buffer will be overwritten.

8.7.1 Calipers

The **Calipers** button displays a pair of calipers for measuring time intervals. Corresponding arrow buttons on the left side of the screen move each caliper and a third button locks the caliper to the trace. Time interval of up to 80 seconds can be measured with accuracy of 5 ms – once locked, the calipers move with the trace and remain even when they are moved off screen. If you have both calipers visible on the screen and then exit and re-enter Review Screen with new snapshot, the Calipers will remain enabled and active and on the same place on the screen to facilitate activation mapping.

8.7.2 Saving ECG Data

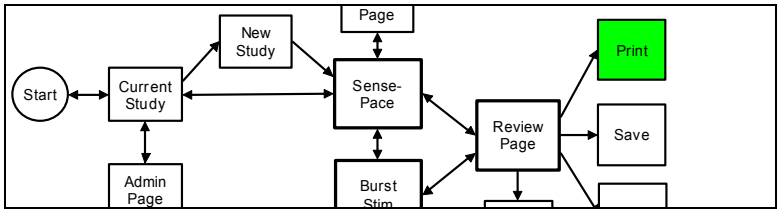
The displayed 80 second snapshot of ECG data may be saved to file by the **Save** button. File numbers are generated automatically in the format “y.dat”, where y is a file number 1, 2…299.

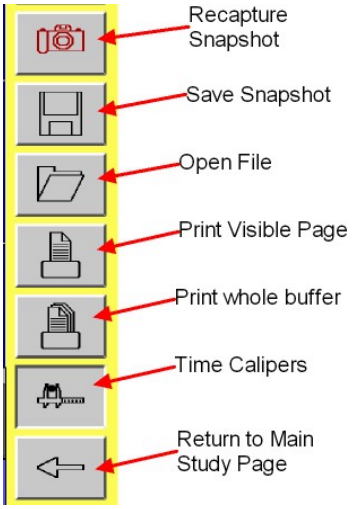
Stored data files are intended to allow inspection of study data off line after the case, but are not permanent. Files are added to when continuing a session but are deleted and restart at ‘1.dat’ when starting a new session.

8.7.3 Loading Stored ECG Data

Load button opens a file browser, which allows selection of which file to open. Information listed on each file include File Number, Date stored, last Ablation Status and Site annotation and first 20 characters of Comment. Only one file may be loaded at a time.

8.8 Printing ECG's





The ORLab™ can print ECG data to Laser printers equipped with HP PCL5e language or emulation.

In the Review Page, you can print part or all of the data.

The **Print** button will print the displayed page at the displayed Sweep Speed and ECG amplitudes.

The **Print Whole Buffer** will print the whole 80 second ECG buffer at the displayed Sweep Speed, after getting confirmation from user.

This printout may produce from 6 pages at a sweep speed of 25mm/s to 24 pages at 100mm/s. A confirmation prompt before printing multiple pages may be enabled from the Administration Page – Print Options.

The printout contains calibrated ECG data, measured ECG amplitudes if selected for display in protocol, sense and pace events and Context Data of Stimulator settings which prevailed at the left side of the page.

Multi-page printouts are numbered 1/x, 2/x, where x is the total number of pages in the printout.

Time marks at the bottom of the graph form a continuous time line across pages and are labeled with the seconds of the time when signal occurred. Time at the left page border (to the nearest second) is displayed as the Captured Time at the left top corner of each page.

Refer to Figure 17 below for an example of ECG printout.

AtriCure

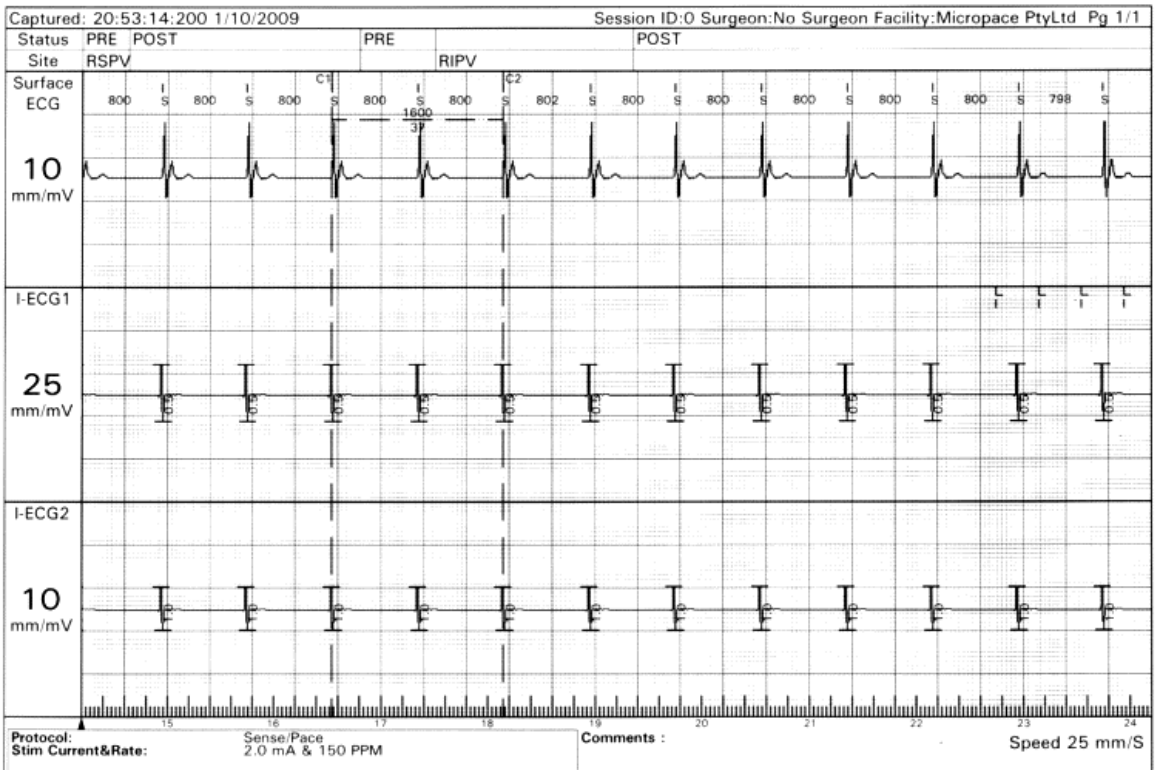
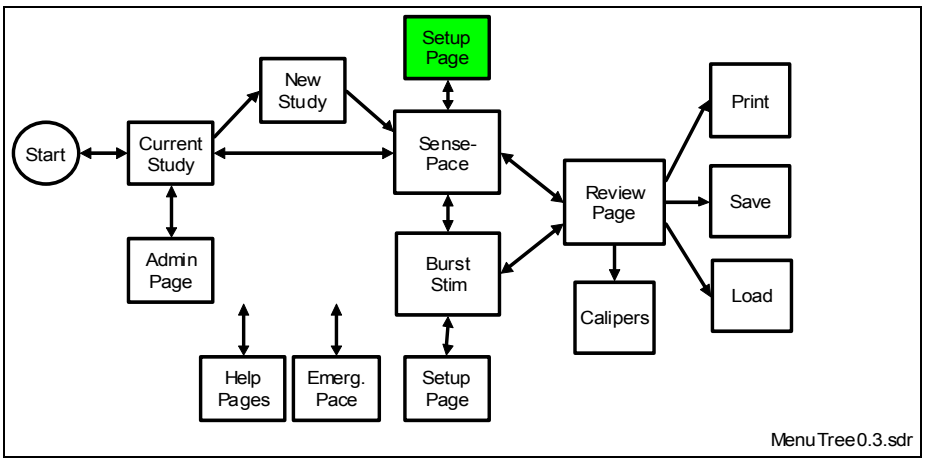


Figure 17 Example of a Printout

8.9 Configuring ORLab™ Protocols



Press the Setup button in either the Sense Pace or Burst Stim protocols to enter their own Parameter Setup Page.

The following parameters are available to control basic protocol functions in each protocol.

8.9.1 Setup available for Sense Pace Protocol

The Sense-Pace Protocol may be further controlled from its **Setup Page**. These parameters control the sensing channel for QRS and Rate detection, Stimulation channel, synchronization of first stimulus sensed QRS and parameters for QRS detection.

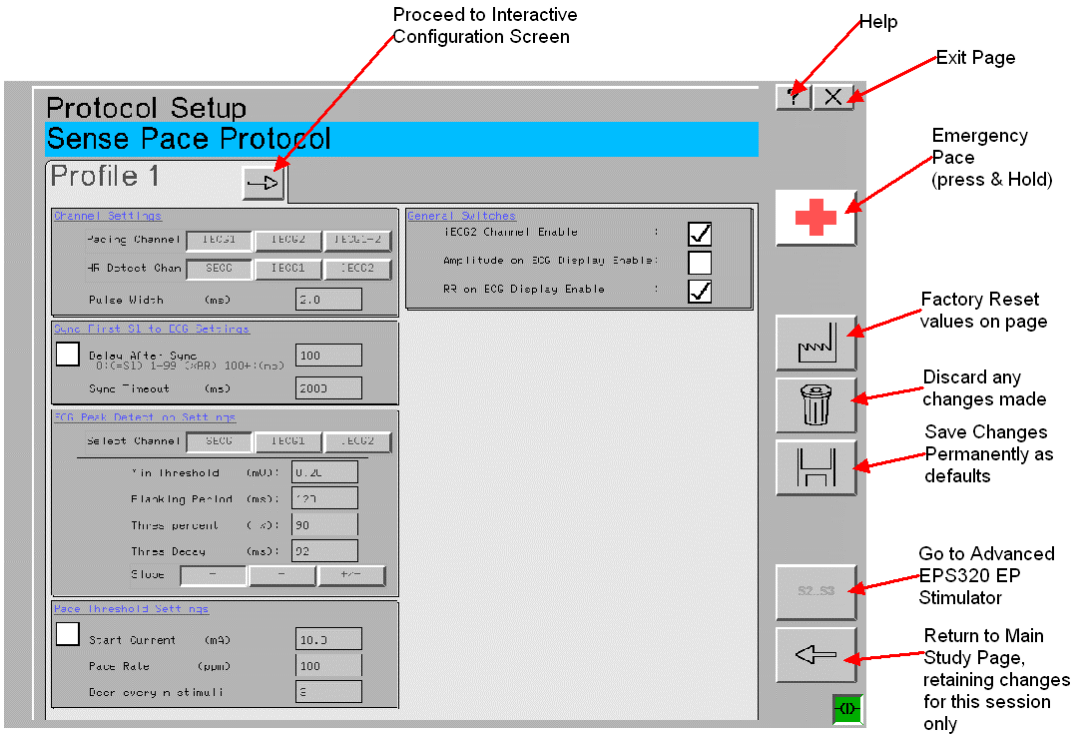
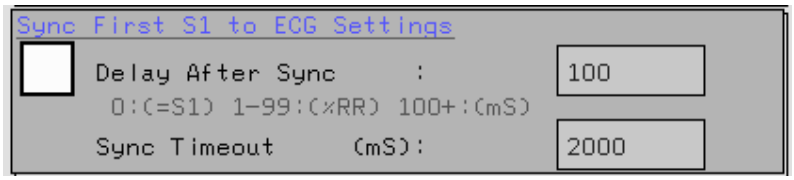

Proceed to Interactive Configuration Screen
Help
Exit Page
Protocol Setup
Sense Pace Protocol
Profile 1
Emergency Pace (press & Hold)
Factory Reset values on page
Discard any changes made
Save Changes Permanently as defaults
Go to Advanced EPS320 EP Stimulator
Return to Main Study Page, retaining changes for this session only

Figure 18 Sense Pace protocol Setup screen

Channel Settings

Pacing Channel Settings:	(i) iECG1 or (ii) iECG2 or (iii) iECG1+2
Rate Detect Options:	(i) Surface ECG or (ii) iECG1 or (iii) iECG2
Stimulus Pulse Duration:	Range: 0.5,1,2,3…to 10ms, Default 2ms

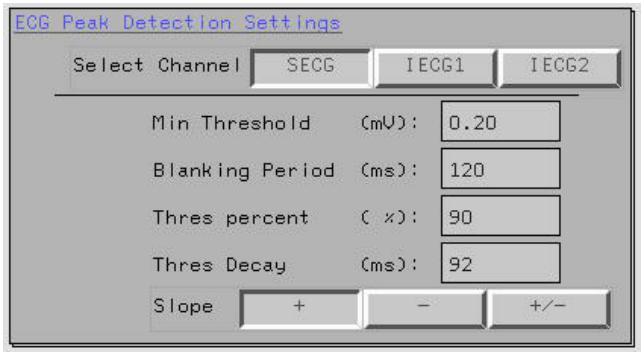
Sync pacing to QRS Settings



Sync 1st S1 of Train to ECG:

1. Enable / Disable Tick Box, also controlled from Main Study Page with QRS Sync button.
2. Delay first stimulus after Sync, Possible delay values
   a. 0 = will be set to same as pacing interval
   b. 1 to 99 = delay in % of RR interval
   c. 100 to 500 = absolute delay in ms
   d. Range: 0-500, Default: 0
3. Sync Timeout
   a. Range 100 to 5,000ms, default 2000ms

ECG Peak / QRS detection settings



The following parameters control the sensitivity of peak detection:

1. Min Threshold, [iECG: Range ±0.01 to ±18.0mV, default: ±2mV; sECG: 0 to ±7.0mV, default 2mV]
2. Blanking Period, [Range 50-1000ms, Def: 180ms]
3. Post-peak Threshold, [Range 0 to 99%, Default 80%]
4. Threshold Decay, [Range 0 to 99%, Default 50%]
5. Minimum Threshold is controlled also by the QRS Peak Detection Minimum Threshold Up/Down buttons on the Main display (as shown on the right).

Explanation of QRS Detection Parameters:

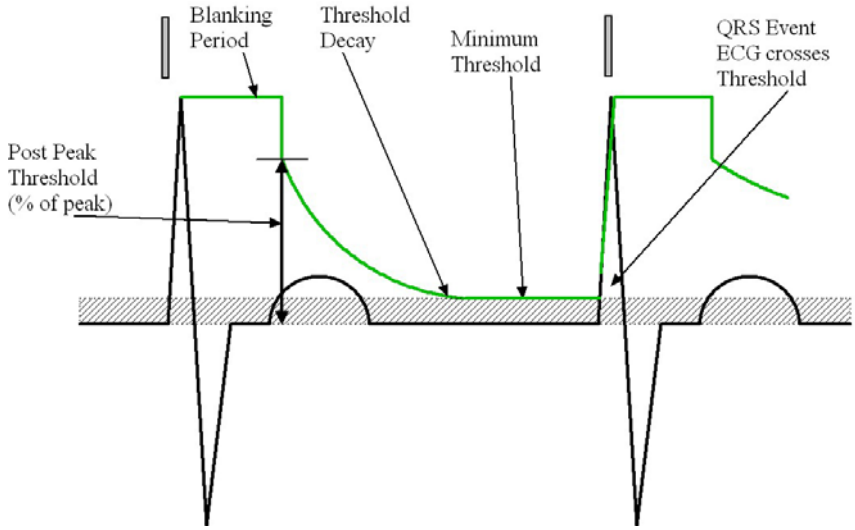
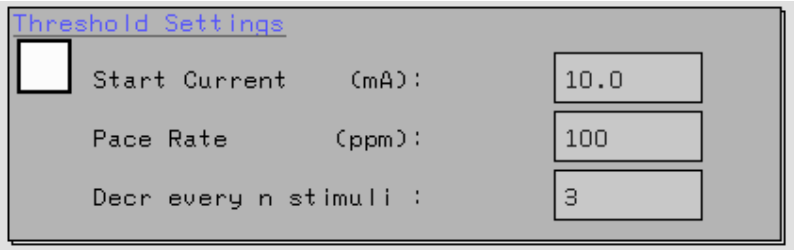


Figure 19 ECG Peak detection parameters

Pacing Threshold Settings



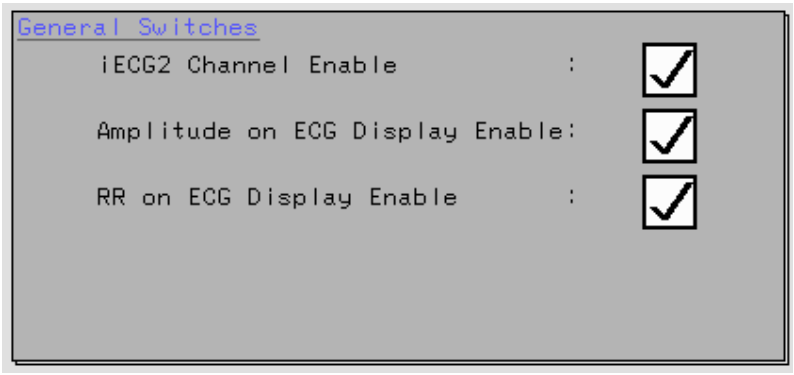
Pacing Threshold Module:

Activated by pressing **Pace-Thrs** Button on Main Study Page.

Adjustable parameters are:

1. Starting Current Amplitude, [Range:0.5 to 25mA, Default 10mA]
2. Default Pace Rate [Range: 20-350ppm, Default 80ppm]
3. Number of pulses between decrements in Current amplitude [Range: 1 to 99, Default: 3]

Other Control Switches



General Switches:

iECG Channel enable:

Uncheck to disable display of iECG channel 2 on the screen if you have no useful signal on that channel.

The channel however gets recorded and may be viewed in review mode regardless of this switch.

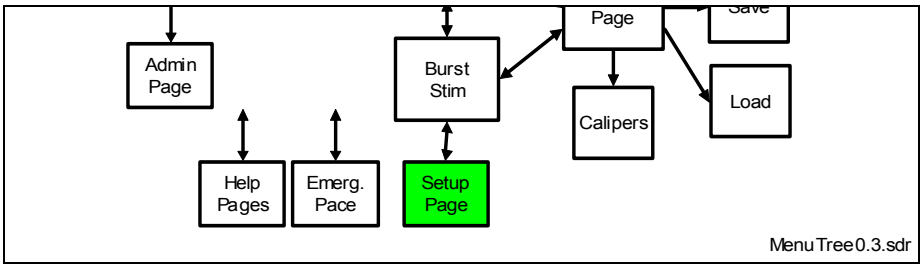
Amplitude on ECG Display Enable

Toggles On/Off the display of measured electrogram peak amplitudes.

RR on ECG Display Enable

Toggles On/Off the display of measured RR intervals on electrogram.

8.9.2 Setup Page for Burst Stim Protocol



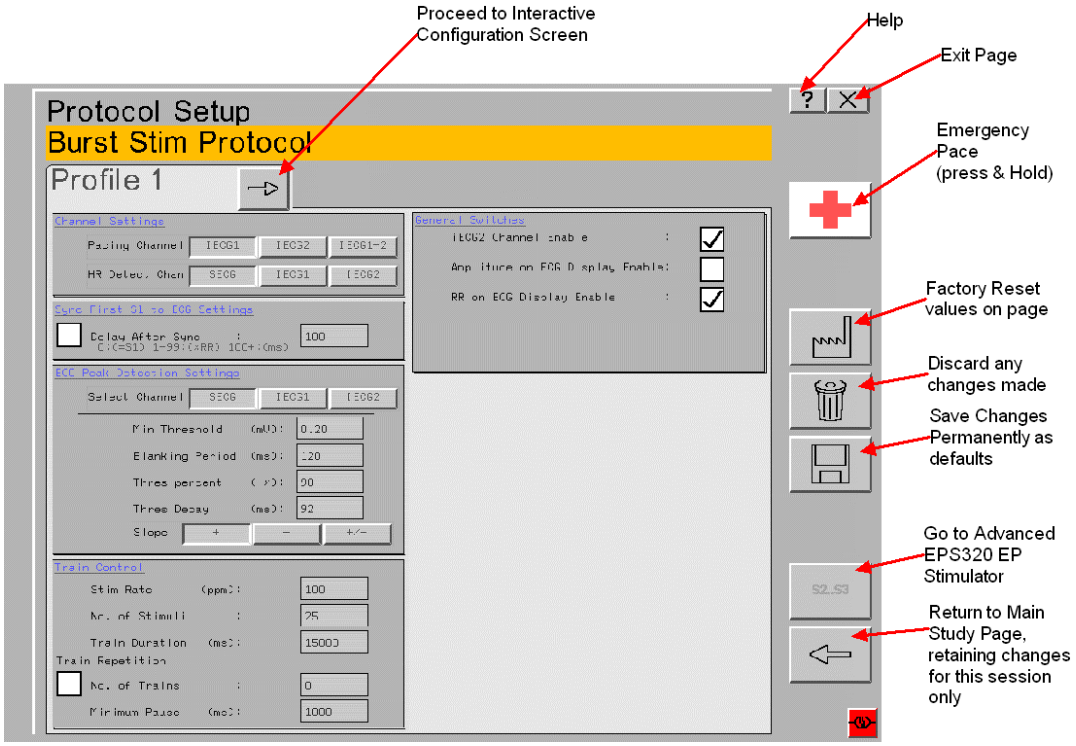
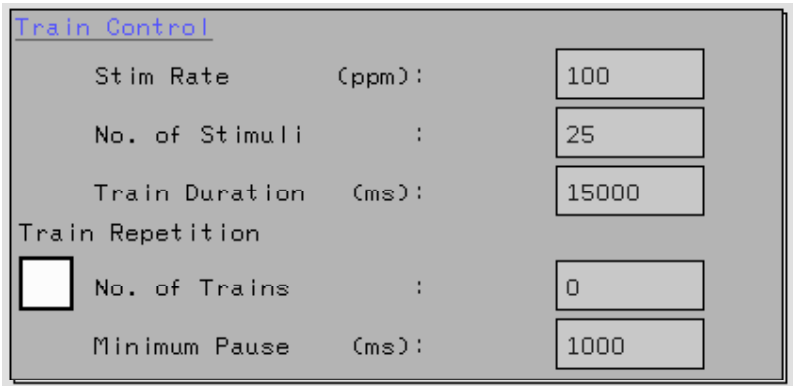

Proceed to Interactive Configuration Screen
Help
Exit Page
Protocol Setup
Burst Stim Protocol
Profile 1
Emergency Pace (press & Hold)
Factory Reset values on page
Discard any changes made
Save Changes Permanently as defaults
Go to Advanced EPS320 EP Stimulator
Return to Main Study Page, retaining changes for this session only

Figure 20 Burst Stim Setup Page

Burst Pace Train control



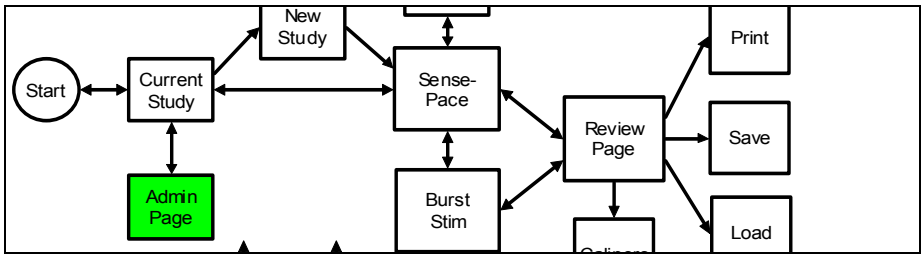
Train Control Module: This allows control of predefined trains of High Frequency stimuli.

1. Parameters are:
   a. Stim Rate: Range 100 to 1800ppm, Default: 100ppm
   b. No. of Stimuli: 1 to 999, Default: 25
   c. Resulting Train Duration:(display only)

Train Repetition Module: This allows control of repetition of trains before pacing stops.

1. Tick box enables or disables feature.
2. Trains may be repeated a specific number of times.
3. Parameters are:
   a. Number of Trains: 0: infinite train, 1 to 99, Default: 0
   b. Minimum Pause (between trains): 0 to 9999ms, Default: 0ms

8.10 Service set up on entry screen – Administration Page



The Administration Page allows adjustment of system Data and Time and editing of Facility and Surgeon's names in the drop-down names list. It also gives access to Touch Screen Calibration.

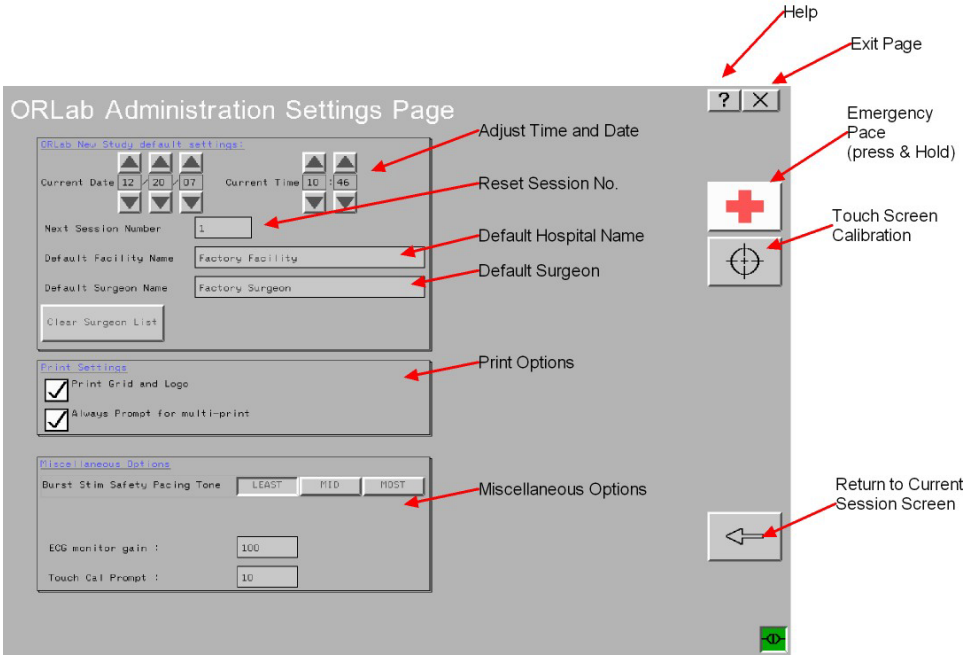
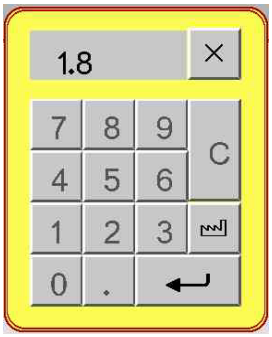


Figure 21 Administration Page

Adjust Time and Date	Adjust ORLab's time base to current one. Date is in US Style: mm.dd.yy
Session Number	Number is auto-incremented on every new session in order to continue the numbering sequence of the facility. User can change with password (contact Micropace EP,Inc.). Number resets to 1 in case of software re-installation.
Default Facility Name	Touch to set Facility Name.
Default Surgeon Name	Touch to add surgeon name to a drop down list. List can be cleared and re-entered but entries cannot be individually edited.
Printing Options	If using graph paper, un-tick Grid and Logo option. Always prompt on Multi-print will always ask for confirmation when printing the whole buffer.
Burst Stim Safety Pacing Tone	Enables safety warning before stimulation in Burst Stim mode. On pressing PACE button, causes a delay of 0.7 sec and a warning tone prior to commencement of stimulation. Value: **LEAST**: Warning occurs only on first burst stimulation in any session. Value **MID**: Warning tone issues again after every re-entry into Burst Stim Protocol. Value **MOST**: Warning re-issues if no stimulation occurs for 5 minutes.
ECG Monitor Gain	Enter amplification factor for external ECG Monitor signal being used for Surface ECG in ORLab. range: 20 to 1000, default: 100.

Touch Cal Prompt	If you touch the screen this many times without hitting a valid button, ORLab will prompt you for recalibration of screen.

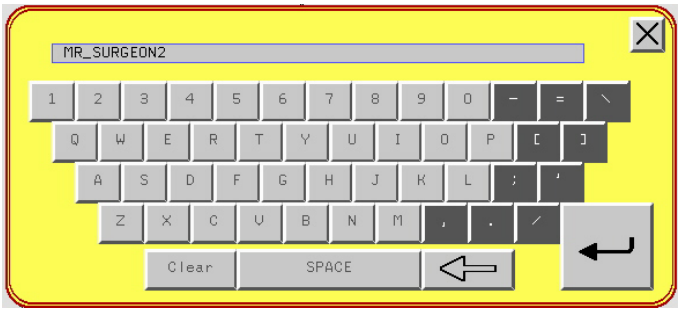
8.11 Keyboard and Numeric Keypad



To modify a numeric parameter, touch the numeric field to display a Numeric Keypad for data entry.

The Numeric Keypad indicates the allowable range for the parameter and any error messages. A Factory Preset button allows setting of the Factory Default if you are not sure of the appropriate value.

Alphanumeric parameters such as Facility name and Surgeon's name on Admin Page and Comments field on the Review Page, display an on-screen keyboard for data entry. Up to 35 characters may be entered.



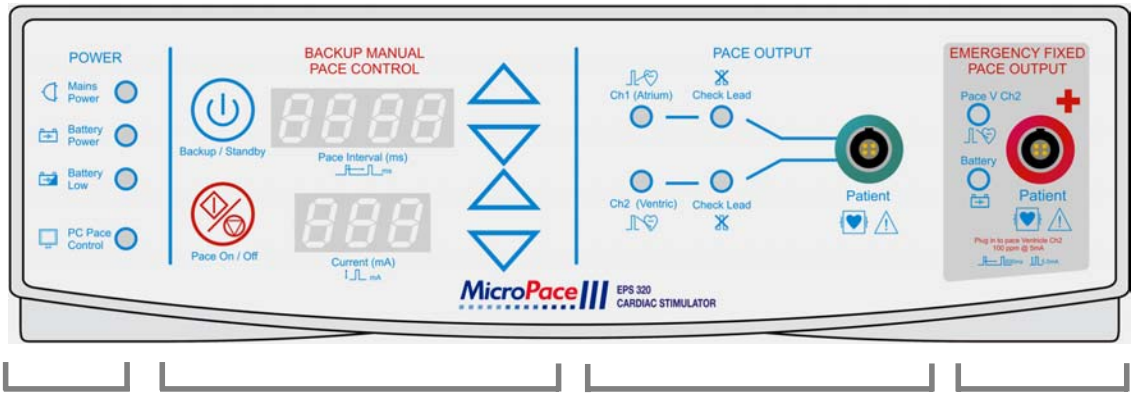
9. THE EPS320 STIMULUS GENERATOR UNIT

The pacing current is generated in the Stimulus Generator Unit (SGU) and has two independent channels, which are designated Atrial and Ventricular corresponding to the PACE_SITE options in the EPS320 Stimulator Software or Pacing Channel settings (IECG1 and IECG2) in the ORLab™ Stimulator software. Both channels are identical and can be used to pace any cardiac chamber, however, it is recommended that the ventricular channel be primarily used to pace the ventricle because the Emergency Fixed Pace Output paces only the Ventricular channel.

The SGU is connected to the serial COM1 port on the computer using a custom made RS232 connection cable.

9.1 Stimulus Generator Unit layout

The front panel, shown in Figure 22 has four sections described below from left to right:



POWER LED's | Backup Manual Pace | Normal Pace Output Green socket | Emergency Pacing

Figure 22 The EPS320 Stimulus Generator Unit front panel

Four power indicator lights on the extreme left:

(i) Main Power (green/yellow)
- GREEN ON - mains power is connected and unit switched on at the POWER switch, backup battery is trickle changing, Stimulus Generator Unit is in PC CONTROL or BACKUP MANUAL operation mode.
- GREEN BLINKING- mains power is connected, unit in STANDBY mode; backup battery charging.
- YELLOW - Mains power available, but unit switched OFF; backup battery not charging.

(ii) Battery Power (orange) - mains power lost, operating on backup battery. A minimum of 2 hours of operation is expected from a fully charged backup battery.

(iii) Battery Low (red) - battery charge low, only approximately 10 minutes of operation remaining.

(iv) PC Pace Control (green) - Serial RS232 data link is functioning and Stimulator is under control of computer.

Backup Manual Pace Control:

This section located in the left middle of the front panel is a backup system and is normally inactive. Should the computer fail due to power failure, hardware failure or software crash, the Stimulator will detect the loss of communication from the Computer (due to loss of watchdog transmissions) and automatically switches into the Backup Manual Pace mode. This mode may also be manually selected by pressing the BACKUP ENABLE button. The red 7-segment LED numerical display will light up showing default values for Pace Interval (500ms) and Current (5mA). These may be adjusted by the up/down arrows on the right of the display. Pacing may then be toggled on/off by pressing PACE ON/OFF button. Note that pulse width is fixed at 2ms.

Pressing the BACKUP ENABLE button when the Stimulus Generator Unit is already in Backup Manual Pace Mode sends the stimulator to Sleep Mode i.e. low power consumption standby mode. This is the mode that the stimulator adopts on exiting the Stimulator computer program. The Stimulus Generator Unit may be awakened by turning the computer on and running Stimulator software or by pressing the Backup Enable button once more.

Pace Output:

Two green LED's marked Atrium and Ventricle light briefly when stimulation pulse is generated (NB the LED blink duration is made longer than the pacing pulse duration for visibility.

The two LED's labelled Check Lead, signal a high impedance condition during last stimulus pulse, i.e. programmed current not delivered due to very high impedance. This is usually due to a disconnection in the circuit or a broken cable/connection.

The following graphs indicate the maximum deliverable current into given pacing lead impedances and the maximum impedance for a given programmed current, above which High Impedance message will be issued.

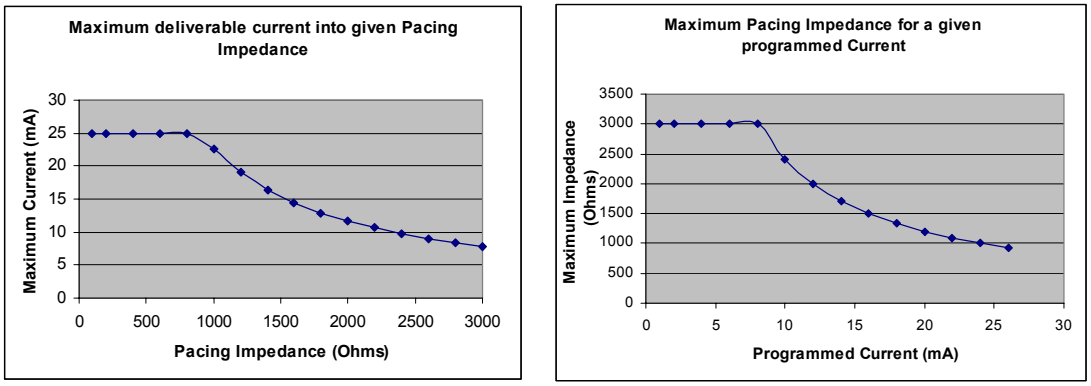


Figure 23 Stimulator output characteristics

Emergency Fixed Pace Output:

This is a last resort backup system. In the unlikely case of the Stimulus Generator Unit itself failing, i.e. the stimulator does not pace even in the BACKUP MANUAL PACING mode and the patient requires urgent pacing, the Operator may pull out the green plug from the PACE OUTPUT socket and plug it into the red EMERGENCY FIXED PACE OUTPUT socket to the right of the PACE OUTPUT socket. The pacing lead impedance automatically turns on the Emergency Fixed Rate Pacing which immediately starts pacing (ventricle only) at 100bpm, with 5mA current and 2ms duration. A loud buzzer will sound between each pacing pulse indicating emergency mode of operation of stimulator.

The BATTERY OK green LED will light after a brief delay of about 2-3 seconds indicating that battery has adequate charge. If it fails to light, then pacing may no longer be reliable and the battery should be replaced at the earliest opportunity. The PACE V green LED will normally blink

with each stimulus. If it fails to do so and/or no sound is emitted by the circuit, then pacing is probably not occurring and the patient should be connected to an alternative external temporary pacemaker as soon as possible.

This emergency circuit is completely independent from the remainder of the stimulator. It is powered by its own 9V Lithium battery with a shelf life of 10 years in standby mode and has independent defibrillation protection.

Information Displayed During Normal Operation:

The two LED 7-segment numerical displays in the Backup Manual Pace section are also used to display information during normal power on self test (POST) and when errors occur (see below).

When the Stimulus Generator Unit is switched on, the unit will normally display the following, in the PACE INTERVAL and CURRENT displays, shown here side by side:

StAn dby	indicating transition to the Standby Mode and then
	Nothing, which together with the lit green MAINS POWER LED, indicates the Standby Mode.

Upon turning on of the computer and the PC connecting to the Stimulus Generator Unit, the display shows the following:

PC tESt	indicating the PC Pace Controlled mode, indicated also by the lit green PC PACE CONTROL.

Upon pressing the BACKUP ENABLE button to activate the Backup Manual Pace mode, the display shows the following sequence of data:

SELF tESt	indicating the self test is in progress,
EPS 320	indicating the model of the device,
VEr 4.68	indicating the firmware version,
BAtt 15.5	indicating loaded battery voltage, and finally,
600 5.0	indicating the default pacing interval and pacing current in the Backup Manual Pace Mode.

9.2 Stimulator Connections

Figure 24 shows the connectors on the rear panel of the Stimulus Generator Unit.

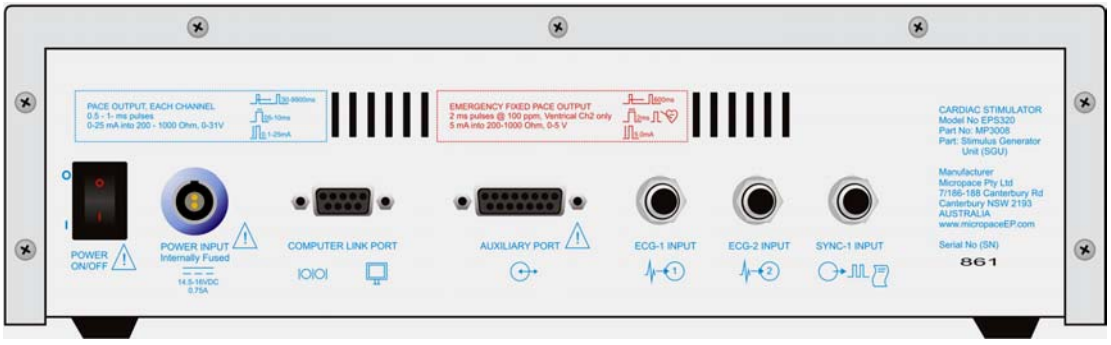


Figure 24 Connectors on rear panel of Stimulus Generator Unit

Power On/Off

This is the main power switch to the Stimulus Generator Unit. In the Off position the units is without power, however, the MAINS POWER indicator glows yellow if external power remains connected to the Power Input socket. In the On position, the unit draws power from the external power supply or if during operation external power fails, then from the internal backup lead acid battery. The SGU is not intended to be powered up from Off state without external power and backup battery alone (except when 100% charged) will generally not power up the SGU from Off state.

Power Input

External Power input. Connect only to Micropace Power Supply, Part No. MP3074. The unit requires 15 VDC power supply at a nominal current load of 750 mA via a Redel 2 pin socket. The unit draws up to 1.5 A at power-on; the unit may not boot-up if voltage drops below about 7 Volts during this surge. The internal lead-acid battery requires a float charge of 14.1 Volts for full charge; supply voltage below 14.3 V will fail to fully charge this battery. Input voltage is reverse polarity protected. Input voltage should never exceed 30V.

Computer Link Port

Serial RS232 data link to computer's COM1 Port; DB9 connector. Use only Micropace Serial RS232 Boost Cable (Part No. MP3033A), as this has EMC and ESD protection built into the computer end D-connector required for compliance with the relevant European Community Directives. Other cables may cause the Unit to radiate unacceptable levels of electromagnetic radiation and/or be susceptible to electrostatic discharge.

The Micropace Serial Boost RS232 cable is a straight-through connected cable; (null modem cable will not function). Only four pins are required to be connected: 2(Tx),3(Rx), 4(Gnd) and 5(DTR-μP Reset).

ECG-1 Input & ECG-2 Input

High level ECG 6.5mm phone jack inputs. Input voltage range is 0 to 5 Volts, and source impedance should be less than 10 KΩ. Gain may be configured with the CONFIG VAR 28 'ECG gain Ext1' variable for input voltages of 1V or 2V. ECG sensing may be selected from either of these external ECG Inputs (or from the pacing electrodes of either pacing channel) via the SENSE_SITE menu. The ECG will become the source for the hardware or software QRS detector and will be displayed on the screen. The ECG is sampled with 8-bit accuracy at 500 samples per second.

Sync-1 Output

This port delivers a CMOS logic (positive 5V) logic 200 ms logical pulse at various times during stimulation. It is provided to allow use of the common 6.5mm Phone plug connection system.

Auxiliary Port

This port allows connection to above ECG Inputs and Sync output as well as two further Sync outputs and two Sync inputs via a single DB15 connector. It may also be used to control the Stimulus Multiplexer Box. Refer to the Service Manual for details.

9.3 Hardware Error Messages on the Stimulus Generator Unit.

Hardware errors appear on the 7-segment LED displays labelled 'Pace Interval' and 'Current' and indicate operational failures concerning the Stimulus Generator Unit.

Most of these errors are preceded by a 'countdown to error' phase, signalled by a countdown from 7 to 0 in the lower window, when pressing the 'Pace On/Off' button attempts to reset the error. If you suspect a false alarm due to interference, for example, you have applied RF ablation very close to the stimulation electrode, press the Pace On/Off button to attempt to reset the error and continue to use the stimulator.

Most of these errors, except the communications-related ones, cause a help screen to appear on the computer screen. Refer to Table 8 below.

Error Message	Error Name	Explanation	Suggested action
C,P,U,_,E,r,r	CPU Error	CPU self test failure.	Contact distributor
P,O,r,_,E,r,r	POR Error	Hardware watchdog self test failed	Contact distributor
b,u,t,n,E,r,r	Button Error	One of the front panel buttons/keys are stuck in the ON position.	Contact distributor
S,O,F,t,x,x,x	Software Error	where xxx is any 3-digit number. Software execution miss-flow trap number.	Contact Distributor
_,I,N,t	Interrupt Error	Error in firmware program flow.	Contact distributor
b,A,t,t,E,r,r	Battery Error	Battery has become depleted while unit on Battery power. Stimulus Generator Unit cannot function.	Reconnect external power and press Backup Enable button.
b,A,t,t,,L,O	Battery Low	Backup Battery < 8.6V during self test. The Stimulator will not function on backup battery, 1.e. it will not function without external power.	You may continue to use the Stimulator if you have external power connected. The internal battery will charge during use.
E,b,a,t,E,r,r	Emerg. Batt Error	Emergency Battery self test failed.	Contact the Distributor, or your biomedical engineering department to have Battery replaced.
t,E,S,t,E,r,r	Test Error	Self Test failure of stimulus generating or safety circuits.	Contact distributor
r,A,t,E,E,r,r	Rate Error	High Stim Rate detected. Unit has detected apparently unintended two pulses less than 300 ms apart. This may be due to noise on the stimulator output (e.g. RF ablation voltage) or the communication cable.	Disconnect Stimulator from the patient. Check that communication cable between PC and Stimulus Generator Unit is secure and remove any interference from the stimulator outputs. Reset Stimulus Generator Unit by pressing 'Backup Enable'. If error persists contact distributor.
_,d,c,_,E,r,r	DC Error	DC Output detected. This may be due to output channel failure or noise on stimulator output (e.g. RF ablation voltage). This may cause unwanted arrhythmias.	Disconnect Stimulator from the patient. Remove any interference from the stimulator outputs. Reset Stimulus Generator Unit by pressing 'Backup Enable'. If error persists contact distributor.

Error Message	Error Name	Explanation	Suggested action
_,t,o,L,E,r,r	Tolerance Error	Pulse Tolerance Error. More that 200 pulses were out of the +/- 25% tolerance limit.	Remove any interference from the stimulator outputs. Reset Stimulus Generator Unit by pressing 'Backup Enable'. If error persists contact distributor.
N,o,P,C,E,r,r	No PC Error	No communication received from PC for a while. Due to failure of PC or disconnection of the communication cable.	Check that communication cable between PC and Stimulus Generator Unit is secure. Restart both the Stimulus Generator Unit and the PC by switching them off and on.
r,E,r,r ,E,r,r	Receive Error	Serial RS232 data link receive errors	Noise on the data link between Stimulus Generator Unit and the PC. Check the cable.

Table 8 Tabulated Error messages

10. TROUBLESHOOTING

Micropace Stimulator software does not start on turning on the computer.

(i) If computer does not respond to touching the Touch screen, check all cable connections and then power down and power up the computer. If the computer still does not respond then the computer may need repair.

Pacing is not capturing and no stimulus artifact is seen.

(i) If Atrium or Ventricle LEDs are flashing on the Stimulus Generator Unit on the appropriate channel:

- If the Check Lead LED is flashing, then the Stimulator is most probably working correctly and there is a break somewhere in the catheter or wiring or, possibly but unlikely, pacing wire is not in contact with myocardium.

(ii) If Atrium or Ventricle LEDs are not flashing on the appropriate channels:

- If the Mains Power LED is not green, but is yellow, the Stimulus Generator Unit is switched OFF - switch it on at the rear panel. If the LED is not lit at all there is a problem with the power supply/mains power connection - check this and restore power.
- Check the connection between the Computer and Stimulus Generator Unit.
- Finally, change the Stimulus Generator Unit Mode to BACKUP MANUAL PACE mode by pressing the BACKUP ENABLE button. Press PACE ON/OFF once. If the Stimulus Generator Unit paces both channels and Atrium and Ventricle light, then there is a problem in the Computer or the communications link. Contact your Distributor for further help.

Patient is not capturing but a stimulus artifact is visible.

(i) Consider current may be inadequate, try increasing current output.

- If the Check Lead LED is flashing, then the pacing wire is not in contact or is touching infracted myocardium and needs repositioning or may have high impedance due to a broken conductor.

Regular pacing produces irregular stimulus symbols on the screen.

(i) This may occur if you were altering a parameter repeatedly during rapid pacing, or continuously pressing a key and is due to the computer having insufficient time to attend to all these low priority tasks, which includes sound-generation. Actual Stimulus timing, however, will be accurate because the software gives it the highest priority.

The Generator does not pace, 'dC Err' appears on Stimulus Generator Unit.

(i) Cause of problem:

- A 'dC Err' appears on the BACKUP MANUAL PACE LED display and a pulsed high-pitched sound is emitted. This signifies a hardware or firmware failure in the Stimulus Generator Unit causing possible continuous stimulation of the myocardium - i.e. DC current on the output. This could potentially induce ventricular fibrillation - disconnect the patient by unplugging the green patient lead from the Pacing Output connector on the front of the Stimulus Generator Unit.

(ii) Emergency pacing:

- If emergency backup pacing is required, you can use the EMERGENCY FIXED PACE facility by plugging the patient lead into this red socket (see above).

Troubleshooting the Touch Screen

(i) The ORLab™ software detects and verifies presence of Touch Screen; if touch function is missing, system informs user and halts.

(ii) If touch screen is blank:

- Verify that display is switched on at the power switch on the side of the screen and Bona PC is switched on.
- Verify that video cable is attached between the touch screen and Bona PC.
- Substitute another LCD touch screen – if image appears then the touch screen is at fault, otherwise the Bona PC may be at fault.

(iii) Touch screen displays picture but is not responsive:

- Verify serial COM cable from touch display to computer is connected into COM2 of Bona PC.

(iv) If LCD Touch screen does not respond appropriately to touch whereby it activates unexpected menus or parameters,

- The LCD Touch screen probably requires recalibration. Go to Current Study Page, then to Administration Screen (Spanner icon) and select the Cross Hairs icon to calibrate screen. Follow its instructions carefully. If situation is not resolved, the touch screen may need repair.

11. MAINTENANCE

11.1 Batteries

(i) The Backup 12V lead-acid gel battery trickle charges from the external Power Supply during pacing. You should therefore always run the Stimulator with the External Power Supply connected. Expected life span of the type of battery supplied is about 4 years and it should be replaced every 3 years. If the Stimulator is used on battery power, ensure that the battery is recharged before the next clinical use (a fully depleted battery takes approximately 20 hours to recharge; charging continues during use of stimulator).

(ii) Ensure that EMERGENCY FIXED PACING OUTPUT functioning is checked once every 6 months, either at routine maintenance or by using it briefly during an EPS study to ensure that patient capture is effected. The computer checks the emergency battery on every power up and warns the Operator if low. This battery must be replaced after 7 years from the date of manufacture, as the expected life span of the type supplied is 10 years.

(iii) Replace the Emergency Fixed Rate pacing 9V battery if Batt OK indicator fails to light during pacing or 7 years after date of manufacture with an Ultralife U9VL, 9V lithium manganese PP3 style battery from Micropace or Farnell PN 299390.

(iv) Replace the Backup 12V battery 3 years after date of manufacture with a Yuasa/Genesis NP2.3-12-FR, 12V 2.3 Ah sealed lead-acid battery, from Micropace or Farnell PN 174786. Battery should be disposed of in an approved disposal or recycling facility for lead and acid-containing products.

(v) A Battery Replacement Information label may be found on the underside of the SGU.

(vi) The Emergency 9V battery contains no lead and may be disposed of with the rest of the unit in compliance with the applicable local waste control regulations.

11.2 Maintenance and Calibration

(i) Suggested weekly preventative servicing:

- Inspect, clean and check the Touch Screen for correct operation.
- Inspect all cables for damage – such as crushing from trolley wheels.

(ii) Annual preventative servicing should include:

- Calibration. Stimulus Current and Duration accuracy should be checked every 12 months. This is performed by placing a 1kΩ (1%) resistor across the channel output posts and measuring with an oscilloscope the Current amplitude and duration for set values throughout their range. Calibration is factory preset by use of 0.1% voltage reference, 0.1% resistors and an A to D converter. There is only one adjustable component per channel in the Stimulus Generator Unit - zero current offset; this affects accuracy of current only in the range of 0.1 to 0.5mA. If incorrect parameters are found then the Stimulus Generator Unit requires servicing by qualified personnel.
- Perform electrical safety tests to UL/IEC60601-1 using a suitable commercial tester, in particular verify (i) summation of the earth leakage current does not exceed 50 µA, (ii) patient isolation and patient and mains on applied part leakage currents, measured preferably at bedside patient output box to include entire installation, or at Stimulator outputs.

- Checking batteries for signs of damage or loss of function and replacement of inadequate batteries or those due for replacement.
- Checking LED's function on POST.
- Ensuring that all external cables are not damaged and are securely fastened into their receptacles.
- Cleaning the computer's cooling grille, cleaning externally by vacuum cleaning is acceptable.
- Running the ROMDOS chkdsk.exe utility software on hard disk C: to diagnose any bad sectors; do not attempt to fix any errors – contact the distributor if errors found.

11.3 Cleaning Instructions

(i) The ORLab™ Stimulator should be kept clean to ensure reliable operation.

(ii) The Stimulator is not protected against ingress of liquids and the Operator should protect it from contamination, particularly by blood and spillage of fluids such as beverages into the Stimulus Generator Unit or the computer. Any spillage should be cleaned immediately and the unit sent for service as soon as possible to minimize damage to components.

(iii) All ORLab™ components may be externally cleaned using a cloth dampened with standard hospital equipment cleaning agents such as 10% ammonia or 10% bleach, isopropyl alcohol, Cidex, or mild soap. Do not spray or pour agents onto the equipment and do not use acetone solvents.

(iv) Touch Screen

- The Touch Screen is not suitable for sterilization. Cover Touch Screen with sterile plastic bag if it is to be part of a sterile field to prevent ingress of liquids or body fluids.
- To clean the touch screen, use window or glass cleaner. Put the cleaner on the rag and wipe the touch screen. Never apply the cleaner directly on the touch screen.
- Do not use alcohol (methyl, ethyl or isopropyl) or any strong dissolvent. Do not use thinner or benzene, abrasive cleaners or compressed air.
- To clean the display unit cabinet, use a cloth lightly dampened with mild detergent.
- Avoid getting liquids inside your Touch Screen. If liquid does get inside, have a qualified service technician check it before you power it on again.

11.4 Serviceable Life and Disposal

(i) The ORLab™ Stimulator and accessories have an expected life span of 7 years and will be supported by Micropace at least this period.

(ii) Upon decommissioning, the lead acid battery should be removed from the Stimulus Generator Unit and disposed of in an approved disposal or recycling facility for lead and acid-containing products. The Emergency 9V battery contains no lead and may be disposed of with the rest of the unit in compliance with the applicable local waste control regulations. If you have any questions about disposal, contact Micropace or its distributor. Recycling Passport document is available on the Micropace website www.micropaceEP.com.

(iii) EU-wide legislation as implemented in each Member State requires the waste electrical and electronic products carrying the mark (*right*) must be disposed of separately from normal household waste. This includes monitors, and electrical accessories, such as signal cables or power cords. When you need to dispose of your Micropace ORLab™, please *contact the Distributor or Micropace directly.*

12. ORLAB™ SPECIFICATIONS

i. System

Stimulus Controller:	Embedded micro-controller in SGU
User Interface:	PC windows-style graphical display
Weight	25 kg gross
System Power:	110-240VAC 50-60Hz, 900W max. (50W standby), Class I
Isolation transformer:	Toroidal 1:1 medical grade, 110-240 VAC, 1000 VA max.

ii. Computer

CPU:	VIA-Eden ESP™ 533 MHz or similar
Weight:	5.65 kg, with Touch Screen
Dimension:	CPU: 23.4x4.8x17.5 cm, 15" Touch screen Monitor
Hard Disk:	128Mb Compact Flash Card
Power Source:	100-240 VAC to 12V DC 5.0A PSU (via isolation transformer)
O/S Software:	Custom RTOS / Datalight ROM-DOS

iii. Stimulus Generator Unit

Main power source:	100-240 VAC to 15 VDC 2 A PSU
Backup power:	12V 2.1 Ah sealed lead acid
Emergency power:	9V $LiMnO_2$i PP3, 10y life
Weight:	5.3 kg including batteries & PSU
Dimensions:	31.5cm x 34.0 cm x 9.5cm
Power Consumption:	800 mA peak during operation 40 mA in standby mode
Operating Time:	Indefinite with mains connected Two (2) hours on backup battery

iv. Pacing Channels

Isolated Channels (3):	(i) Chan 1 and (ii) Chan 2 via green Redel 4 pin socket (iii) Emergency Fixed Pace Output to Ventricle, via red Redel 4 pin socket
Power Source:	Internal DC-DC converters
Circuit Isolation:	Compliant with IEC60601-1, Class CF, 5kV impulse proof
RF Energy Protection:	Protected up to 180VAC at 500kHz (150W into 300 Ohms load).

v. Computer Controlled Stimulus Pulses

Current:	0.1 to 25 mA
Current Steps:	0.1 mA
Accuracy:	± 2% or ± 0.2 mA, which ever is greater
Pulse Duration:	0.5 ms, 1-10 ms in steps of 1ms
Accuracy:	± 0.15 ms
Load Impedance:	200-1000 Ω, <700 Ω for max current
Max Output Voltage:	27V
Pulse Shape:·	Square wave monophasic pulse, pacing bipole discharge via 10ms post-stim pulse output short and 10kΩ stimulator output impedance.

vi. Inter-stimulus Intervals

Pace Rate Range:	30-350 ppm (Sense Pace) 100 – 1800 ppm (Burst Stim)
Stability:	Quartz computer clock, ± 30 parts per million @ 25° C
Extra-Stimuli:	6 max, S2-S7, independent
Coupling interval:	30 - 9990 ms
Accuracy	± 1 ms or 0.1% whichever is greater

vii. Pre-programmed Protocols / Parameters

- Sense Pace Protocol allows PV isolation testing
- Pace Threshold
- High Frequency Burst Stimulation
- Emergency Pace
- Labels for PV and GP anatomical sites

ix. Backup Manually Controlled Stimulation

Power Source:	12V 2.1Ah sealed lead acid battery
Pulse Current:	0.1 to 25mA
Accuracy:	± 2%, or ± 0.2mA, which ever is greater
Pulse Duration:	2ms, fixed
Pulse Interval:	100 - 1400ms, accuracy:±1%

x. ECG Sense/Trigger

High level external -	
Two inputs:	(i) Ext_ECG1, (ii) Ext_ECG2,
Connector:	6.5mm Phone socket
Input Ranges:	1V and 2V pp for FSD, max ±2.5V
Frequency Range:	1 to 250 Hz, typical
Pacing catheter tip -	
Two channels:	(i) Chan 1, (ii) Chan 2
Input ranges:	2mV, 5mV, 10mV, 25mV, 38mV for FSD, Hw Gains: 800, 400, 200, 50
Frequency Range:	10 to 250 Hz, typical
Either Source -	
Threshold:	Adaptive software peak detect
Lockout Period:	50 - 1000ms in software
Pace Sync Delay:	50 - 5000ms in software
Sampling- display:	500Hz, 8 bit

xii. ECG Display

Chan 1 (sECG):	5, 10, 20 mm/mV
Chan 2 & 3 (iECG):	1, 2, 5, 10, 25 mm/mV
Display Accuracy:	(input of ±5 mV): <=±10% of FSD or <=±100µV, whichever is greater
ECG Display height:	50 mm (2.0") 180 pixels
Sweep speed:	25, 50, and 100 mm/s, accuracy better than ±5%
Event Markers:	QRS and Pace events marked
ECG Time Calipers:	0 to 80 seconds, 5 ms resolution
ECG amplitude:	Automated measurement,< 38mV

xii. ECG Printout

Printer	Laser Printer, Letter or A4 size
Printable data	Print one screen or whole 80 sec record.
Printout content:	3 ECG channels, event markers, RR intervals, anatomical labels
Print time:	< 5 sec per page

xii. Emergency Backup Pacing

Power Source:	9V Lithium Manganese PP3 battery, 10 years life
Pacing Pulse:	5mA ±1.0 mA, 2ms ±0.5ms, 100 ±20 ppm
Pace output:	Separate red Redel 4 pin socket
Control:	Pacing activated by connection of a load <1MΩ, i.e. insertion of plug connected to patient

xiii. Environmental

Operating T° Range	+5ºC to +35ºC (30% to 80% RH)
Storage T° Range	-10ºC to +60ºC (10% to 85% RH)
Storage altitude:	1 Atm to 13,000 m

xiv. Certification

MDD Device Class:	Class IIb
IEC60601-1	certified
EMC compliance	certified
CE Marking	certified
US Regulations	510(k) Accepted

Notes: 1. Specifications may change without notice
2. Computer specifications will vary according to availability

ORLab Specifications Ver 1.4b, 11.Apr.2008
EPS320B-EU/US, PCB Ver P3.15 Sch Ver 3.09

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13. MANUFACTURER'S GUIDANCE AND DECLARATION–ELECTROMAGNETIC EMISSIONS

This product complies with EN/IEC60601-1-2:2001.

13.1 Cable Lengths

The following Micropace Cables Comply with:

- RF emissions, EN 55011, Class B/Group 1
- EN 60601-1-2: 2001

WARNING: The use of accessories or cables other than those specified may result in increased emission and/or abnormal function of the Micropace ORLab™.

Micropace Part No.	Signal Cables	Length
MP3014	Stimulus Connection Box	2.5m (8.2')
MP3033A	RS232 Boost Serial Cable	2.0m (6.5')
MP3034	ECG Signal Cable	2.5m (8.2')
MP3109	BNC to Phone Cable	2.5m (8.2')

Cables included with accessory PC (Personal Computer) and LCD Display comply with their respective manufacturer's declarations.

13.2 EMI / EMC Specifications

- Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents (see below).
- Portable and mobile RF Communications Equipment can affect Medical Electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Micropace ORLab™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Micropace ORLab™ should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	The Micropace ORLab™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Micropace ORLab™ is suitable for use in all establishments, including domestic, and those connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC 61000 3-2	Class A	
Voltage Fluctuations / Flicker Emission IEC 61000 3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Micropace ORLab™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Micropace ORLab™ should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short	❑ <5% Ut (>95% dip in Ut) for 0.5	Not applicable	Mains power quality should be that of a typical commercial or

interruptions and voltage variations on power supply input lines. IEC 61000-4-11	cycle ❑ 40% Ut (60% dip in Ut) for 5 cycles ❑ 70% Ut (30% dip in Ut) for 25 cycles ❑ <5% Ut (>95% dip in Ut) for 5 sec	Not applicable Not applicable Not applicable	hospital environment. If the user of the Micropace ORLab™ requires continued operation during power mains interruptions, it is recommended that the Micropace ORLab™ be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Micropace ORLab™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Micropace ORLab™ should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 800 MHz	V1= 3 Vrms E1= 3 V/m	Portable and mobile communications equipment should be separated from the Micropace ORLab™ by no less than the distances calculated/listed below: D = (3.5/V1) √P D = (3.5/E1) √P, 80 MHz to 800 MHz D = (7/E1) √P, 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Micropace ORLab™ is used exceeds the applicable RF compliance level above, the Micropace ORLab™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Micropace ORLab™.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Micropace ORLab™

The Micropace ORLab™ is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the Micropace ORLab™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Micropace ORLab™ as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter W	150 kHz to 80 MHz d = [3.5/3] √P	80 MHz to 800 MHz d = [3.5/3] √P	800MHz to 2.5 GHz d = [7/3] √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.70	11.70	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.